Proposal sample writing (full proposal follows)

Sample 1:

Key Players – Hearables Market

Apple and Samsung continue to dominate the hearables market. *Table 2* shows the relative standings of these competitors by shipment volume, market share, and year-over-year growth.

Table 2: Top companies in the hearables market and their performance by shipment volume, market share, and year-over-year growth [19].

Top 5 Wearable Companies, Hearable Devices only, by Shipment Volume, Market Share, and Year-Over-Year Growth, Q2 2019 (shipments in millions)

Company	2Q19 Shipments	2Q19 Market Share	2Q18 Shipments	2Q18 Market Share	Year-over-Year Growth
1. Apple	15.9	50.2%	5.0	55.2%	218.2%
2. Samsung	3.3	10.2%	0.9	10.2%	252.1%
3. Xiaomi	2.1	6.5%	0.3	2.8%	714.8%
4. Bose	1.8	5.7%	0.5	5.1%	288.1%
5. ReSound	1.6	5.1%	0.7	7.7%	132.9%
Others	7.1	22.3%	1.7	19.0%	310.5%
Total	31.8	100.0%	9.1	100.0%	250.0%

Source: IDC Worldwide Quarterly Wearables Tracker, September 9, 2019

Commented [AN8]: I know we covered this earlier, but you'll find out in the next class why most of these appropriated visual explanations are poorly designed. Nothing to worry about right now. The content is excellent.

Competitive Advantages of Apple

Apple possesses several **competitive advantages** that may allow it to overcome the common obstacles of cost, accessibility and stigma that prevent many people with mild to moderate hearing loss from entering the market:

- **Leveraging hearables technology for an OTC device at reduced cost**. With a pair of hearing aids averaging $4300, cost remains a significant barrier for many people living with hearing loss. Apple offers their AirPods and AirPods Pro for $149 and $249.

- **Accessibility**. Until now, getting a hearing aid required finding a hearing professional, getting an assessment, and entering the arduous process of being fitted for a hearing aid. OTC hearing aids will streamline this activity. Apple's strong branding as a leader in consumer electronics transfers well to this segment. Its unrivaled name recognition has eluded key players and products in the hearing aids market. Apple will benefit from its reputation for simplicity and high quality. The trust engendered by their global image is backed up by a strong online presence that provides customers with easy access learn about and buy Apple products. In addition, retail Apple stores have been established around the globe for in-person sales and customer service assistance.

- **Stigma**. Many people are resistant to hearing aids because they fear they will make them look and feel old. Aging adults are far more likely to embrace products associated with 30-year-olds than with products associated with 80-year-olds. Apple's new AirPods are the type of product to break this barrier. As *Table 2* shows, they have world-wide appeal, topping the hearables market while enjoying a year-over-year growth of well over 200%. With an AirPods-like OTC hearing aids product, Apple could integrate hearing aid technologies into their market-topping hearables product providing a young and hip image for OTC hearing aids.

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Sample 2:

Technical Feasibility

Apple is the global leader in the hearables market and has dominated sales with its AirPods wireless earbuds since their fall 2016 launch. When Apple added AirPods Pro with noise cancellation, **transparency mode**, and **live listen**, initial demand was greater than expected and both production and sales continue to increase.

Using its experience in the hearables market along with the insights and abilities gained through collaborations with hearing aid manufacturers, Apple can add an AirPods OTC into the AirPods family. Apple's yearly R&D spending has grown from $1 billion in 2009 to more than $15 million in 2019. It has invested in a range of technologies including wearables, augmented reality, artificial intelligence and more. While some additional research and development will be needed to design a product that meets the final regulations established by the FDA for OTC hearing aids, Apple already has a wealth of expertise from its earlier AirPods experiences.

Financial Feasibility

Since Apple's product development team has run through the Apple new products process for earlier AirPods products, much of the design, engineering, and manufacturing is known. This knowledge and experience will reduce time and costs including salaries, materials, and operational costs. Apple's AirPods products are expected to reach $175 billion this year.

Market Conditions

The OTC hearing aids act recommendations from the FDA are expected to be issued this summer and finalized in spring 2021. This change in the hearing aids market is the result of pressure and interest for an OTC hearing aids option. The low penetration rates of conventional hearing aids manufacturers

among the 48 million Americans with mild to moderate hearing loss provide a compelling opportunity for Apple to destigmatize OTC hearing aids by providing a product that is indistinguishable from the status symbol that AirPods have become around the globe. In addition, the cost of an AirPods-like OTC hearing aid is a fraction of the cost of conventional options. Once AirPods OTC hearing aids are launched, high interest and sales are expected along with growing demand over the long term.

Recommendation

Apple is excellently positioned to bring to market a popular and desirable OTC hearing aid. Building on its hugely popular AirPods family of hearables products, Apple can continue to expand its reach outside of iPhone and Mac sales. With strong name recognition and a reputation for quality and simplicity, Apple will create trust and confidence in its OTC hearing aids and move into the familiar position of sales leader. Coordinating the launch of this product with the implementation of the OTC hearing aids act will allow Apple to take the lead in this new sector and maximize its position within it.

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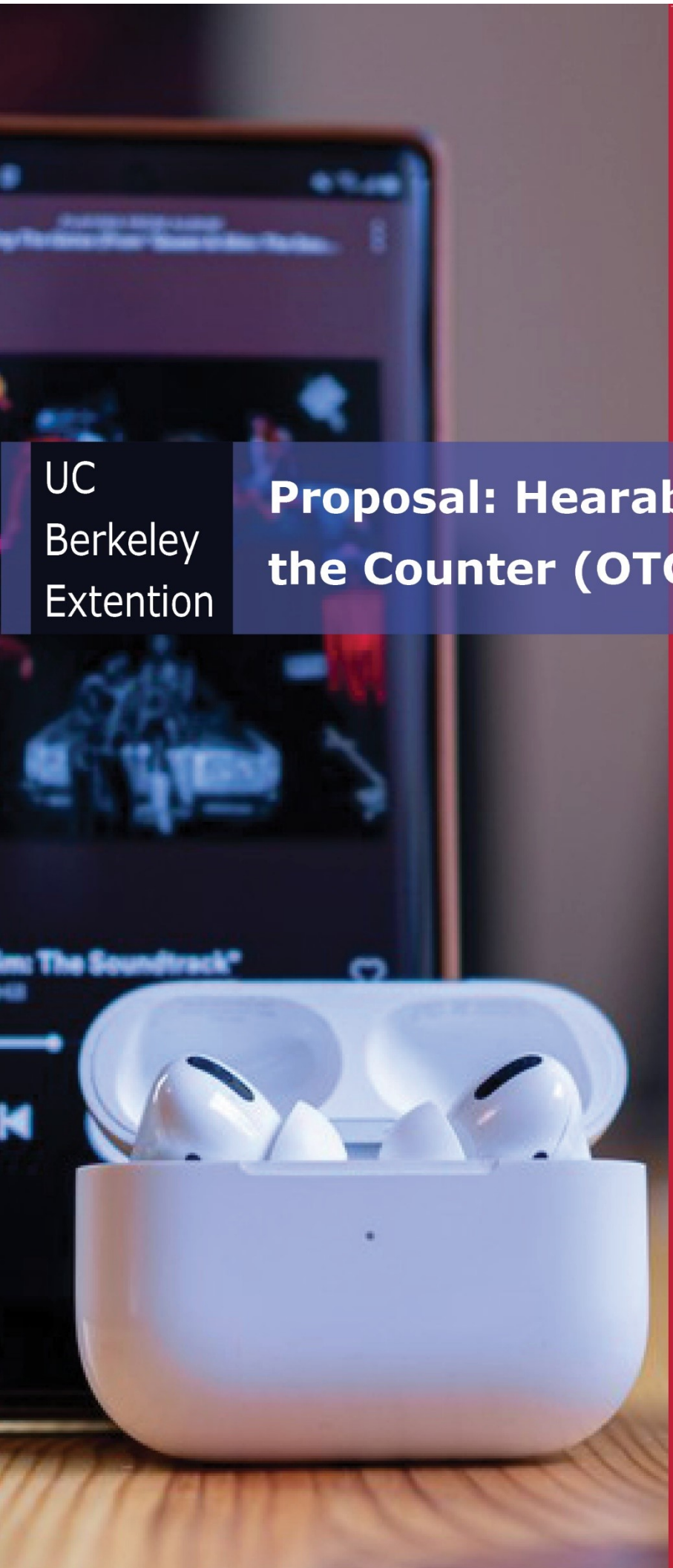

UC Berkeley Extention

Proposal: Hearables as Over the Counter (OTC) Hearing Aids

20 March 2020

Prepared For:
Jeffrey Williams
Chief Operations Officer
Apple Inc.

Prepared By:
Jodi Solomon
Director, Project Management
Apple Inc.

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Executive Summary

Background

Apple is the largest and most profitable tech company in the world. Since its inception in 1976, Apple has grown from a computer company into a multinational tech giant that designs, develops, and sells consumer electronics, computer software, and online services. These products and services are consistently developed with a focus on simplicity and innovation. At its core is a philosophy and culture that promotes a constant effort to expand into markets where it can make a significant contribution. In recent years, Apple has entered into the **hearables**[1] market with its **AirPods** and **AirPods Pro**. Sales of Apple's AirPods and AirPods Pro top the hearables market and are forecast to show a 100% year-over-year increase.

The US hearing aids market is a **consolidated market** due in large part to strict regulations of **medical devices** by the FDA. However, the passage of the **OTC Hearing Aids Act of 2017** will create a new category of hearing aids in the US market, providing an opening in the US market for products sold direct to the consumer that will have reduced FDA regulatory requirements and will be sold without a prescription or professional testing. Once the Hearing Aids Act takes effect, hearables and **personal sound amplifying products** (PSAPs) can enter the **OTC** segment and be marketed as hearing aids. Apple's success in the **hearables** market specifically and in consumer electronics generally position the company as a **market disruptor** and a major player.

Summary

The hearing aids market is a mature, **consolidated market**. High initial investment coupled with the time-intensive demands for research and development (**R&D**) and overcoming governmental restrictions pose a significant barrier to entry. Significantly, the market has not overcome three significant barriers that prevent most potential buyers from entering the market – **stigma**, cost, and complexity.

[1] Terms in boldface type are defined in the Appendix

Apple is well positioned to effectively address these limitations of the status quo. Apple's size and related experience allows it to directly compete with the market's major players. Apple has robust and well-funded R&D programs and products that have proven successful when brought to market. Apple's reputation and branding give it and its products a **"cool factor"** that products currently in the market all lack. Apple's reputation for design simplicity, exceptional performance, and superior customer service will allay fears and perceptions that hearing aids are complicated and difficult to use. Their global online and physical retail stores also help to streamline the process.

Hearables technology provides Apple with the ability to market its hearables products as OTC hearing aids. Apple's collaborations with key players in the **conventional hearing aids market** have provided the company with insights and understandings of the hearing aids market, customer expectations and desires, and product demands. These insights have resulted in hardware and software features for its hearables products that benefit people with mild to moderate hearing loss, like **noise reduction**, **directional sound amplification**, and sweat resistance.

Apple will benefit from entering this new market in three key ways:

- It will assume the position of a key player in the OTC hearing aids segment of the hearing aids market.

- Sales of its OTC hearing aids will create for Apple an additional revenue stream.

- The addition of OTC hearing aids in the Apple products family will strengthen Apple's branding and reputation in the healthcare industry.

Industry Overview:
Medical Technology (MedTech)

Industry Description and Outlook

Definition

The medical technology (**MedTech**) industry, also referred to as the medical devices industry, includes all equipment used in healthcare delivery to diagnose, monitor, and treat medical conditions and diseases. Medical devices range from simple disposables like tongue depressors and bandages, to complex devices like programmable pacemakers and sophisticated imaging systems [1]. Major product categories include neuromodulation and spinal devices, cardiovascular devices, irradiation devices, diabetes devices and supplies, patient recovery and noninvasive materials, and other devices [2].

Industry Performance

As a highly competitive, **high-margin industry** that produces largely nondiscretionary products, the Medical Device Manufacturing industry has performed well over the five years to 2019. Revenue is expected to grow 2.7% in 2019, as an aging population, expanded healthcare coverage, and technological advances bolster market growth [3]. In 2017, global MedTech industry revenue was $438 billion USD (US Dollar) with a **compound annual growth rate (CAGR)** of 6% [4]. *Figure 1* illustrates historical and forecast growth of the industry from 2005 – 2022 [5].

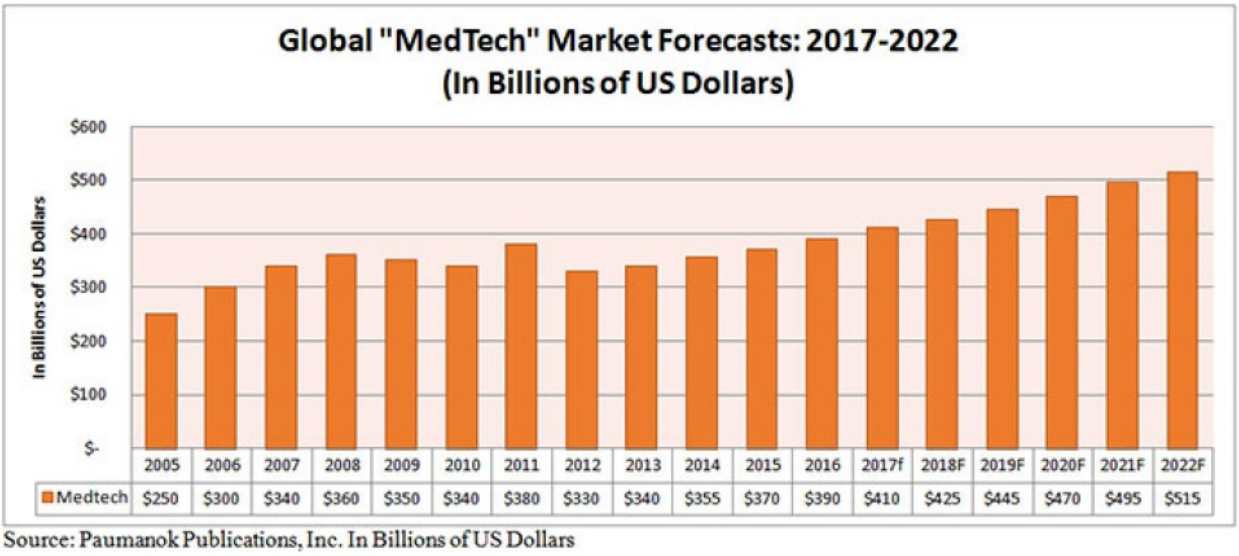

Figure 1. Global MedTech industry value 2005-2016; 2017-2022 forecasts [3].

Growth in the MedTech industry from 2005 – 2016 was largely attributed to the aging populations in western markets and **emerging economies** in countries like Brazil, Russia, India, and China [5]. Additional factors that have affected this industry include healthcare reform, outsourcing, and regulation [3].

Industry Outlook and Forecast

The factors currently influencing growth in the MedTech industry will continue to support forecast growth, as will the continued expansion of medical electronics in the device industry. Government funding, **regulatory framework**, currency fluctuations, and **intellectual property protections** are also important factors that can impact demand for medical devices [3].

Industry Segmentation

The MedTech industry can be divided into 5 product application categories. *Figure 2* shows the size of each sector relative to the overall industry market. **Diagnostic apparatus** is the largest category accounting for 31% of global revenue. **Consumables**, the next largest segment, generates 17% of total revenue [6].

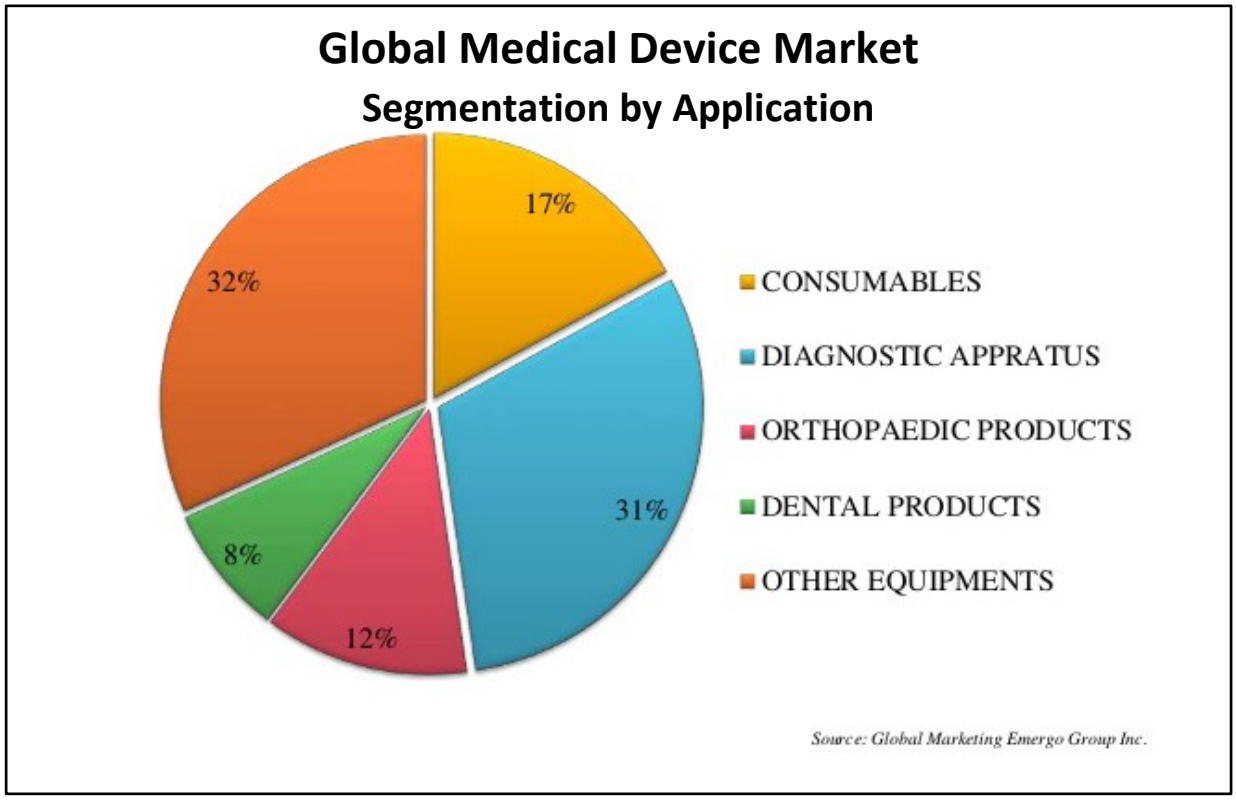

Figure 2. Global MedTech industry segmentation by product application: percent share to global revenue, 2019 [6].

Industry Geographic Segmentation

The global MedTech industry is made up of 5 geographic regions: The Americas, Asia/Pacific, Central/Eastern, Middle East/Africa, and Western Europe. The Americas is the largest segment, owing to the United States, which accounts for almost 40% of the global market [3]. *Figure 3* shows the geographic makeup of the global medical device industry and illustrates the dominance of the Americas, Asia/Pacific, and Western Europe.

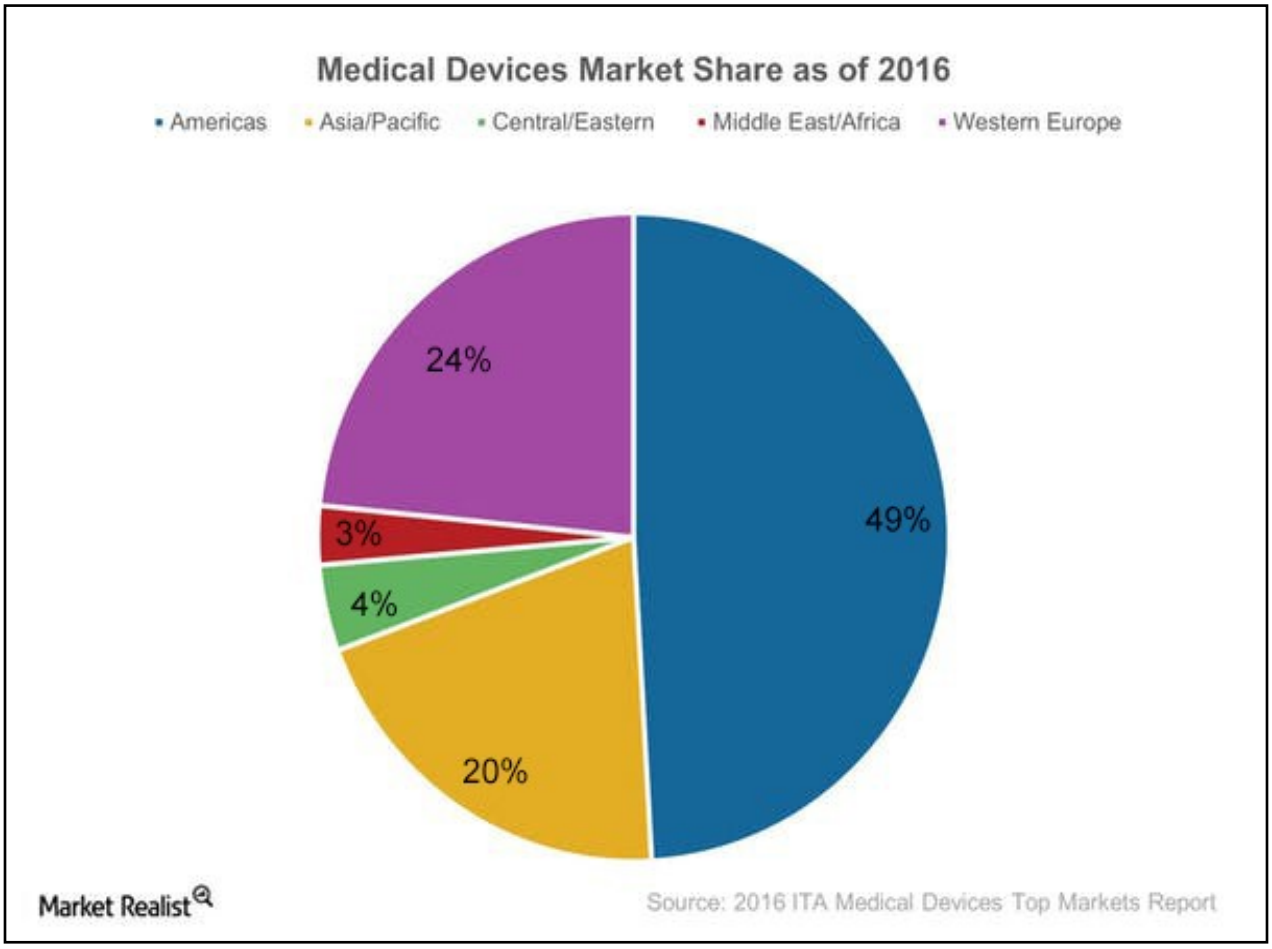

Figure 3. Global medical devices industry segmentation by geography: percent share contribution to global revenue, 2016 [7].

Target Market Analysis: Hearing Aids

Market Description

The hearing aids market manufactures **audiological devices** designed to amplify sound for the wearer, usually with the aim of making speech more intelligible, and to correct impaired hearing. Product categories include CIC (completely in the canal), ITC (in the canal), ITE (in the ear), and BTE (behind the ear) hearing aids, and cochlear implants [8]. OTC (over the counter) hearing aids will become a new category in this market. It was created when Congress passed the Over-the-Counter Hearing Aid Act of 2017. When this law takes effect in summer 2020, products will legally enter the market and customers will be able to purchase hearing aids directly without consulting a **hearing specialist** or obtaining a prescription.

Figure 4 provides the hearing aid products offered and their relative share in the US market:

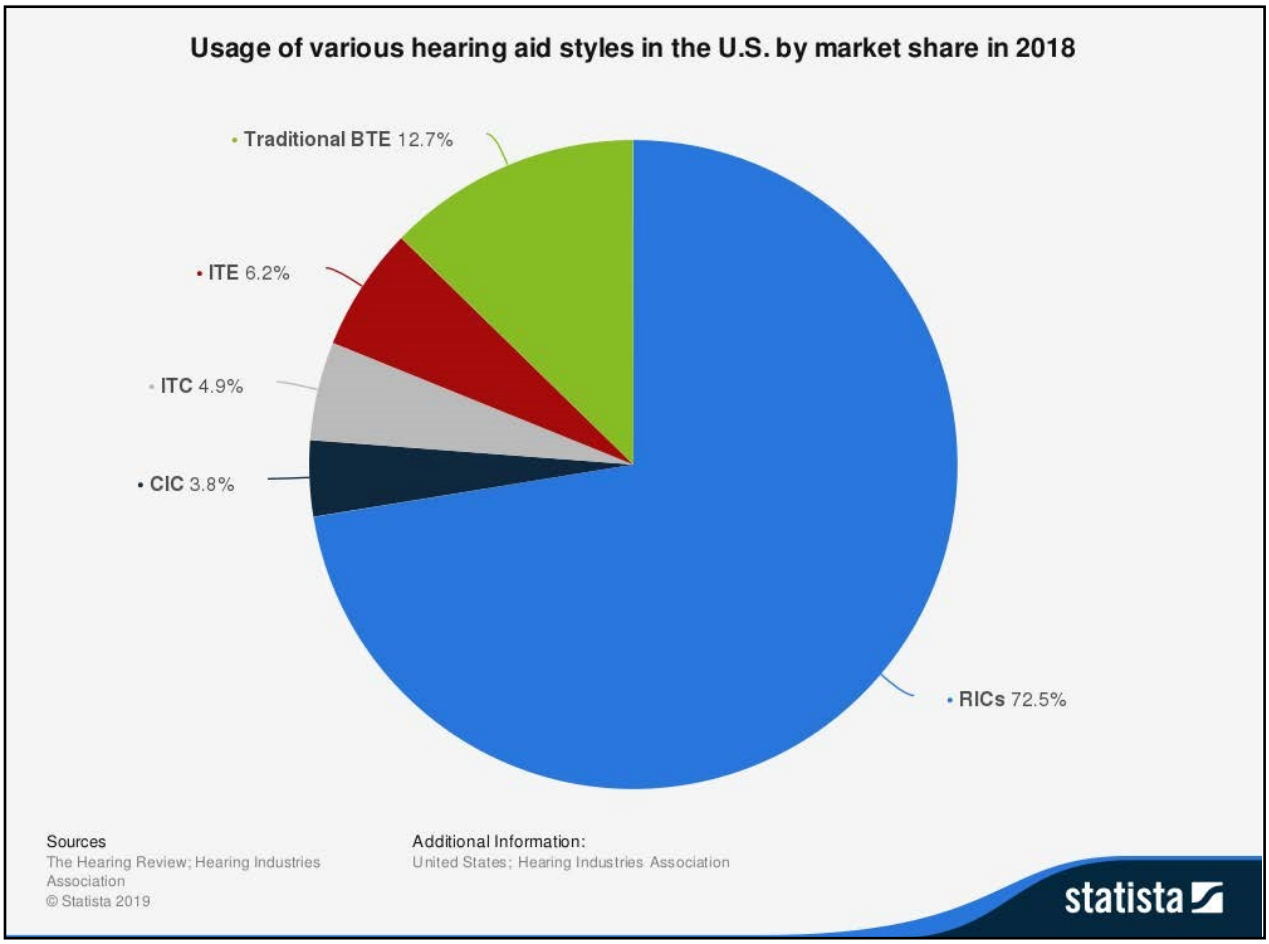

Figure 4. US hearing aids market segmentation by hearing aid type [9].

Market Performance: Current and Historical

In 2018, the global hearing aids market was valued at $7.4 billion (USD) while the US market stood at $1.5 billion (USD) [8]. The US hearing aids market has experienced on average 5.8% growth in the last 5 years and 5.2% growth in the last 10 years [10]. *Figure 5* shows the growth of the market from 2007 to 2018 in the form of units sold:

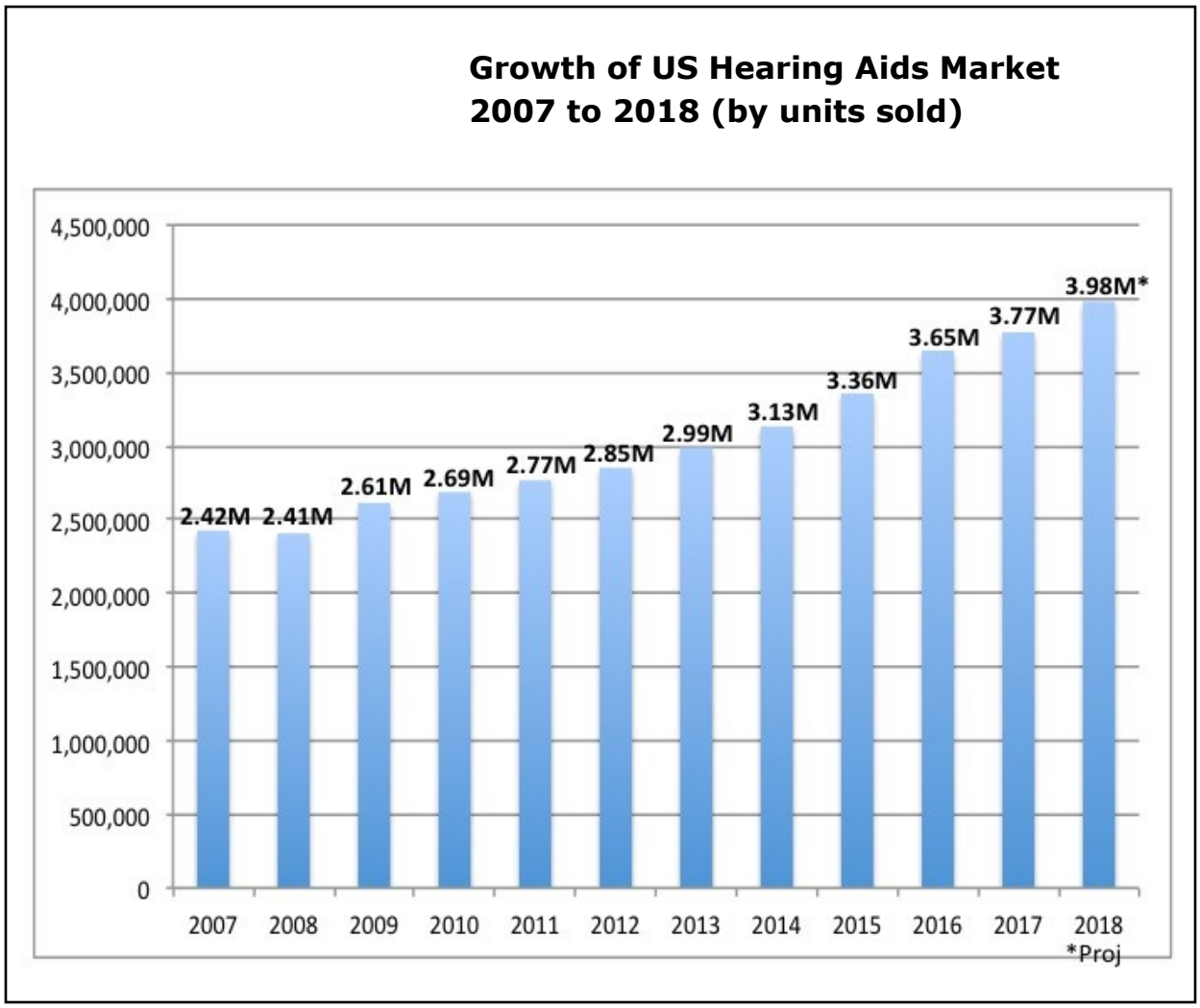

Figure 5. US hearing aid unit sales by year, 2007-2018 [11]. **Source: The Hearing Review (www.hearingreview.com)**

This growth can be tied to an expanding elderly population that "has increasingly required hearing aids to address their age- and chronic disease-related hearing loss" [8]. At the same time, the market is experiencing pressures from warehouse clubs and supercenters, which leverage their buying power to provide low-cost options to consumers. As a result, sales of hearing aids have shifted away from independent audiologists and hearing specialists [8].

Market Outlook and Forecast

Over the next 5 years the US market for hearing aids is forecast to continue to grow, driven by the rising elderly population. However, it is expected that

the domestic hearing aids market will only grow slightly as globally based manufacturers continue to flood the market with low-cost hearing aids [8]. This demand for low-cost options from retailers and wholesalers is expected to hold growth to a CAGR of 0.6% [8].

Market Segmentation

The hearing aids market can be grouped by product type: **RIC (receiver in the canal)** and **RITE (receiver in the ear)**, **ITE (in the ear)**, **ITC (in the canal)**, **CIC (completely in canal)**, and **cochlear implants** (see *Figure 6*).

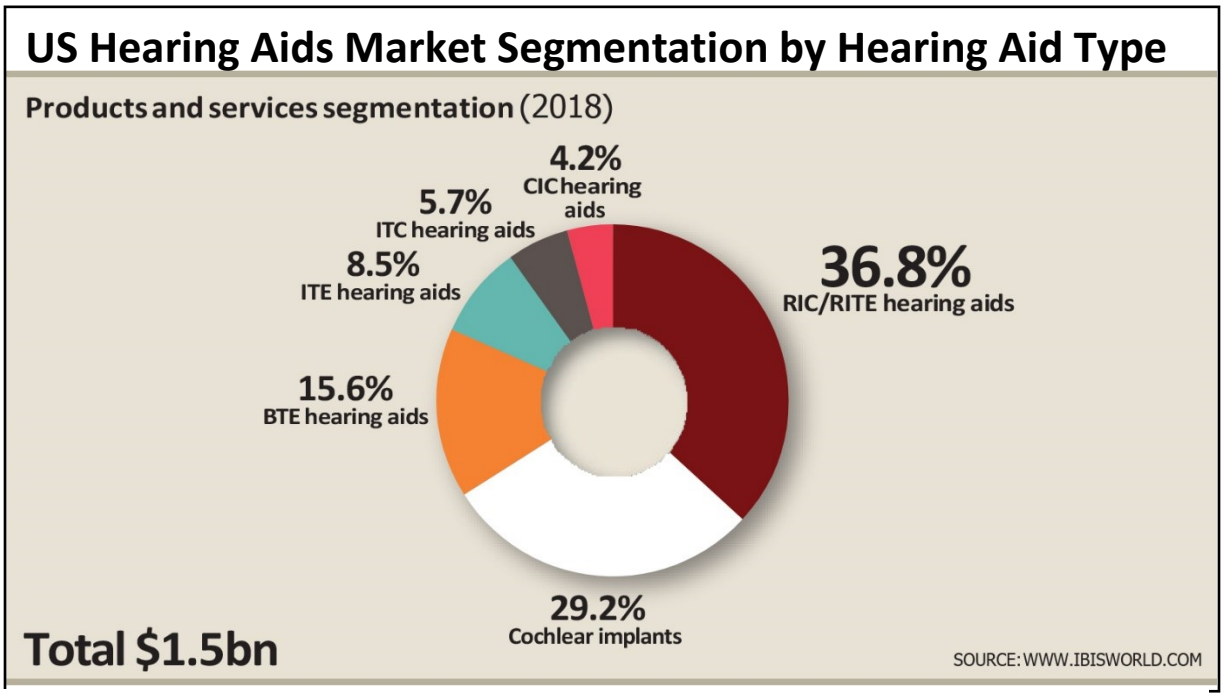

Figure 6. US Hearing Aids Market segmented by hearing aid type showing percent share of total revenue [8].

RIC/RITE hearing aids accounted for 36.8% of total revenue in 2018 and over ½ of all hearing aids sold in the US [8]. BTE hearing aids, which generated 15.6% of total industry revenue, are typically the hearing aid of choice for patients who cannot or will not use products that feature electrical components in the ear canal [8]. ITE and ITC hearing aids, which accounted for 14.2% of the market, are for users with mild to moderate hearing loss.

The US hearing aids market can also be viewed by age demographic: individuals aged 39 and younger, individuals 40 to 69, and individuals 70 and older. *Figure 7* shows the contribution of each age group to the total market.

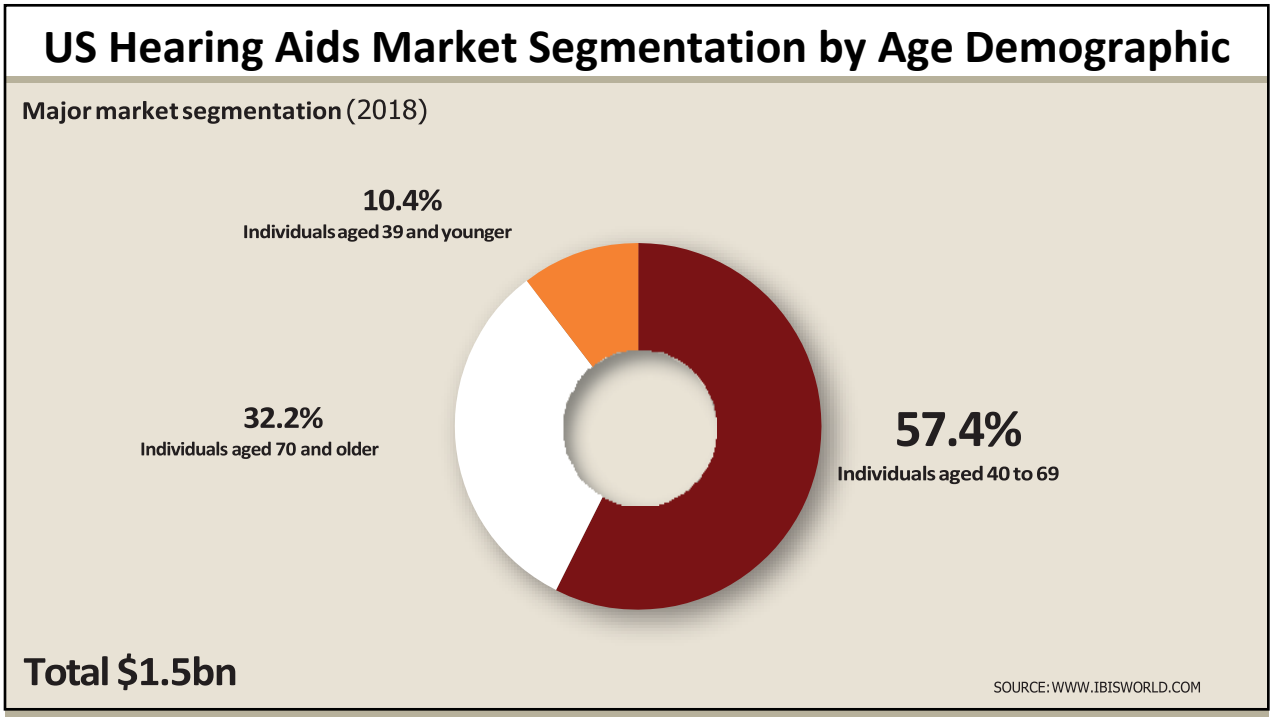

Figure 7. US Hearing Aids Market segmented by age showing percent share of total sales [8].

Individuals 40 to 69 make up the largest segment in the market, contributing 57.4% of total market revenue. This demographic features the highest rates of mild to moderate hearing loss [8]. Individuals 70 and over account for 32.2% of market revenue and possess the highest incidence of moderate to severe hearing loss [8]. Although members of this demographic are slower to adapt to new products than their 40 – 69 counterparts, their demand is likely to grow as more **baby boomers** suffer from impaired hearing and enter the 70+ segment [8].

Market Characteristics

The hearing aids market is highly competitive and highly **concentrated** with products that are technology intensive and very sensitive to innovations and advancements [8].

Market Features

The hearing aids market has the following 3 main characteristics:

- **Market dominated by major players:** The top 4 companies in the hearing aids market accounted for almost 84% of total market revenue in 2018 [8]. Entry into the **mature market** is difficult. Patents are a significant barrier. New entries must develop their own technologies and product designs. In addition to manufacturing facilities, development requires investments in equipment, clinical trials, and approval from governmental authorities.

- **Low rate of use of hearing devices**: Most people who could benefit from hearing devices do not own them. Only 10% of people with mild-to-moderate hearing loss currently use hearing aids [12]. Barriers to adoption include the individual's lack of awareness of diminished hearing, the high cost of hearing devices, and lack of insurance coverage. Social stigma and the perceived difficulty of the process itself are also issues that turn people away from hearing devices.

- **Demographic changes**: The market is increasing in size due to demographic trends. People are living longer and by the time they turn 65 years old, approximately 1/3 of them have hearing loss. For those over 75, that number jumps to 50% [13]. In addition, younger adults are experiencing earlier hearing loss due to exposures to loud sounds, including the effects of in-ear music, cell phone, and other sound delivery by personal electronic devices. The prevalence of hearing loss among teenagers today is 30 percent higher compared to the 1990s. Globally, 1.1 billion people between the ages of 12 to 35 years old are at risk of developing hearing loss [14].

Market Trends

Three trends are impacting the future of hearing devices and their market:

- **Consolidation through mergers and acquisitions (M&A)**: The global hearing aids market has experienced increased merger and acquisition activities, where major players buy key competitors to further strengthen their market position in the highly competitive

market [12]. Hearing aids manufacturers are also acquiring other vendors to enhance their existing product portfolio, enter untapped markets, and increase the customer base [8].

- **New technologies**: Technological innovation in this market is necessary to compete, and it is occurring rapidly. This competition has resulted in the development and production of ever smaller, more comfortable, and technologically advanced products [12]. Enhancements include **feedback management systems**, **noise reduction systems**, and **speech enhancement systems**. On the horizon is the inclusion of **wearable technologies** that track heart rate, brain function, and physical activity [15]. As these innovations come to market, manufacturers can present consumers with a wider array of products that meet consumer's needs regarding budget, features, and comfort [8].

- **New distribution channels**: Historically, hearing devices have been classified as medical devices that trained hearing care professionals prescribed and dispensed. Now, manufacturers are working with **big-box stores**, and hearing-related Internet portals [16]. The Over-The-Counter Hearing Aid Act, as well as the **self-fit hearing aid** category recently created by Bose and its **FDA *de novo* status**, further expand product and service options for consumers [16]. Self-fitting hearing aids offer options to individuals with mild to moderate hearing loss who have not addressed their need. These hearing aids allow users to perform hearing tests and, based on test results, personalize device settings without the expense of professional support or need to access specialized equipment [16].

Market Catalysts

The following factors are propelling the hearing aid market:

- **Rise in geriatric population:** With the increasing aging population, there has been a rising prevalence of hearing loss. Growing **noise pollution** throughout the world also has a significant impact on the hearing abilities of people. **Noise emission** in heavy duty industries,

as well as public concerts, rallies and other loud events, is expected to damage the hearing capacity of adults, thereby resulting in the increase in the demand for hearing aids devices [12]. Over the five years to 2018, the US market expanded, driven by an aging population and improving economic conditions. As the burgeoning baby boomer population ages, more individuals will require hearing aids [8].

- **Technology that improves end-user benefit and self-management:** Hearing aid manufacturers are using new technologies to provide better sound and increase customization by the user. New product lines offer wireless hearing aids, which are embedded with **Bluetooth**, **electromagnetic compatibility (telecoil)**, and **frequency modulation (FM)** compatibility. **Smart hearing aids** are emerging as a popular and effective treatment option for any degree of hearing loss, thereby contributing to the growth of the hearing aids market [16].

- **Expansion of low-cost products**: Hearing aid manufacturers have traditionally needed independent dealers, such as audiologists and hearing aid specialists to get their products in front of customers. However, warehouse clubs and supercenters are rapidly replacing independent dealers as a major downstream market for hearing aid products. These retailers are leveraging their buying power to bring low-cost options into the market and directly to consumers and will continue to exert significant pricing pressures on global hearing aid manufacturing companies [8]. Additionally, online sales are also likely to play a key role in providing consumers various choices and the ability to source products from international manufacturers [8].

Market Disruption

Passage of the Over-The-Counter Hearing Aid Act of 2017 brings to the hearing aids market disruption in the form of a new product category – OTC hearing aids. The scope of this disruption, which will become clearer once the rules and regulations are finalized, may be impacted by:

- OTC hearing aids from the same top companies that currently control the vast majority of market share. Most if not all these hearing aid manufacturers have OTC-type devices and are prepared to compete in this sector [17].

- OTC hearing aids from key players in consumer electronics, like BOSE, Apple, Samsung, and Amazon.

- Devices currently defined and sold as PSAPs (personal sound amplifying products) that meet the OTC Hearing Aid Act rules and regulations.

- Devices currently defined and sold as 'hearables' a sector of the wearables market, "are technically advanced, electronic in-ear-devices designed for multiple purposes ranging from wireless transmission to communication objectives, medical monitoring and fitness tracking" [18].

Competitive Landscape

Key Players – Hearing Aids Market

Four major companies dominate the hearing aids market: William Demant Holding Group, Starkey Hearing Technologies, Sonova Group, and Sivantos Group. *Table 1* shows the relative standings of these competitors in the US Marketplace.

Table 1: Comparison of key players in the US hearing aids market [8].

Company	Headquarters	Brands	Market Share	Revenue (US Market $ Million)	Projected Growth
William Demant	Smorum, Denmark	Oticon Bernafon Sonic Phonic Ear FrontRow Maico Interacoustics Amplivox Grason-Stadler MedRx	38.8 %	576.6	1.5 %
Starkey	Eden Prairie, MN	Audibel NuEar MicroTech	19.0 %	281.7	1.0 %
Sonova Group	Stafa, Switzerland	Advanced Bionics	15.8 %	234.3	2.2 %
Sirvantos	Singapore	Kirkland Signia Siemens Audio Service Rexton A&M Hearing	10.1 %	149.5	4.3 %

Source: IBISWORLD

Figure 8 shows the market share of key players in the US hearing aids market.

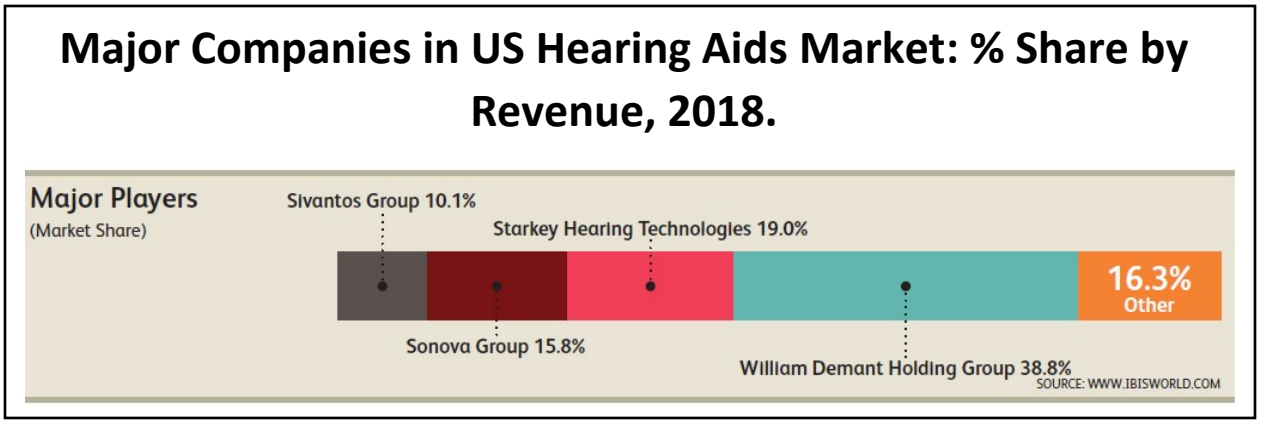

Figure 8. Major players in the hearing aid market: percent share by contribution to revenue, 2018 [13].

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- **Stigma**. Many people are resistant to hearing aids because they fear they will make them look and feel old. Aging adults are far more likely to embrace products associated with 30-year-olds than with products associated with 80-year-olds. Apple's new AirPods are the type of product to break this barrier. As *Table 2* shows, they have world-wide appeal, topping the hearables market while enjoying a year-over-year growth of well over 200%. With an AirPods-like OTC hearing aids product, Apple could integrate hearing aid technologies into their market-topping hearables product providing a young and hip image for OTC hearing aids.

Technical Section

Opportunity Analysis

Limitations to the Status Quo

Three major limitations contribute to a status quo in the hearing aids market that serves just 20% of people with low to moderate hearing loss: the consolidated nature of the market, the high upfront costs to enter the market, and the barriers facing individuals with mild to moderate hearing loss.

- **Consolidated market:** The hearing aids market is a consolidated market with just four key players accounting for nearly 85% of production. Because of this control and the high level of profitability of their devices, market leaders have focused their R&D efforts on improving features desired by current users.

- **High upfront costs:** Due to the current classification of conventional hearing aids as medical devices, manufacturers must undergo testing and operate under a significant layer of government regulation. These regulations create large upfront investments in both time and money for companies looking to enter this market.

- **Consumer resistance:** Most people with hearing loss choose not to address their needs due to the stigma associated with wearing hearing aids and the high initial investment of money and time. The inability to alter the status quo suggests that a new generation of hearing aids and hearing aids delivery is due.

Overview of Hearing Aids

The use of hearing aids provides emotional, physical, and social benefits to people with hearing loss. Reduced hearing is associated with **isolation**,

depression, and **dementia** [21]. The use of hearing aids has been shown to stave off these effects. Hearing aids allow both the individual and the brain to stay active and engaged with the world. An individual's ability to hear and process sounds helps keep the brain fit and may protect against **cognitive decline** [22]. People who wear hearing aids maintain better brain function over time, exhibiting improved **cognition**, balance, and well-being [22]. In addition, hearing aids help people maintain personal and social relationships.

Limitations of Conventional Hearing Aids

Historically in the hearing aids market, a small core group of key players manufacture products that are dispensed through hearing care professionals. While the market has been quick to bring improvements in designs and advances in technologies to market, three core issues continue to limit its reach beyond the historic levels of 10 – 20 percent:

- **High initial costs for testing, evaluation, and devices**: Because conventional hearing aids are regulated and sold as medical devices, the cost often places them out of financial reach for many with impaired hearing. Before obtaining a conventional hearing aid, testing and professional evaluation are required. While some insurance will cover a part or sometimes all these services, a patient's out of pocket costs can range from tens to hundreds of dollars. These fees are in addition to the cost of the hearing aids, which start at $1,000 per device and can go as high as $6,000 per device for a premium hearing aid.

- **High initial investment of time for testing, evaluation, and device fitting**: The time required to acquire and adjust to conventional hearing aids remains a major obstacle. Professional testing and evaluation require one or more trips to a hearing professional. A fitting appointment to select and customize the device can take a couple to several hours. Many conventional hearing aids are made from a custom mold. In these cases, the production and delivery of the custom hearing aids can take up to two weeks. After that, a new hearing aids wearer may need several weeks and as long as 4 months

to adjust to the device and become comfortable with the use and features. During that time, additional appointments will most likely be needed to adjust the device for optimal fit and comfort.

- **The stigma associated with hearing aids and the biases held against hearing aids wearers**: The stigma associated with wearing conventional hearing aids keeps people with mild to moderate hearing loss from addressing their auditory needs. Several interrelated experiences contribute to this limiting factor. Many fear that the use of hearing aids will alter their self-perception - being healthy versus in physical decline, able versus disabled, and smart versus **cognitively impaired** [23]. There also is fear that these same perceptions of hearing aids wearers by others will lead to **ageism**, a term first used by gerontologist Robert N. Butler to describe the discrimination of older adults [24]. Lastly, many adults refrain from conventional hearing aid use out of their desire to not look old [23].

Significance of Limitations on Stakeholders

Limitations in the conventional hearing aids market have established a status quo that supports a consolidated market where manufacturers are not reaching 75 – 80% of people who could benefit from their devices [3]. As a result, both people with hearing loss and the hearing aids market are negatively impacted.

- **Impact on people with hearing loss**: People with untreated hearing loss experience decline in quality of life issues that lead to life-altering changes in their mental, physical, and emotional well-being [21]. Factors including high costs and significant time commitments create a significant barrier for people with mild to moderate hearing loss. The majority – nearly 80% – choose no treatment, and for the 20% who do seek treatment, there is, on average, a 7- to 10-year delay between diagnosis and treatment [25].

- **Impact on the hearing aids market**: While the hearing aids market continues to expand due to the continued rise in the number of people with hearing loss, its growth is limited by its nature as a consolidated

market and its actions as an **oligopoly**. Dominance by a few key players makes the entry of newcomers into this market extremely difficult. Initial investments are prohibitively high. And those that make it into the market are at high risk of being pushed out or absorbed by the incumbent players [26]. Manufacturers continue to focus on growth through technology and design advances while market penetration strategies are largely ignored [26].

Significance for Apple

Apple's standing as one of the largest companies in the world, combined with its robust R & D operations and its hugely successful global branding efforts help protect the company from the limitations associated with conventional hearing aids and the hearing aids market. It has the financial means and the professional talent to enter the emerging OTC hearing aids sector as a market disruptor and major player.

Apple's branding and reputation insulates its products from the stigma associated with conventional hearing aids. "The Apple brand personality is about lifestyle; imagination; liberty regained; innovation; passion; hopes, dreams and aspirations; and power-to-the-people through technology. The Apple brand personality is also about simplicity and the removal of complexity from people's lives; people-driven product design," [27]. Apple products are a **status symbol** instead of a liability. The Apple OTC hearing aid, visually indistinguishable from the AirPods Pro, will carry the same prestige.

Another major advantage for Apple in the OTC hearing aids sector is its expanded distribution capabilities and huge retail reach. In addition to its online presence, Apple has 510 retail stores in 25 different countries [28]. Estimates for 2019 sales of Apple AirPods are 60 million and experts predict that number will double in 2020 [29].

Apple's advantages give it the opportunity to enter and lead the emerging OTC hearing aids sector. Its entry into this new category of hearing aids will reduce the stigma, time, and expense associated with getting hearing aids while expand the market through greater market penetration.

Opportunity Fulfillment: Hearables as OTC Hearing Aids

Hearing Aids for Mild to Moderate Hearing Loss

Overview of Hearing Aids for Mild to Moderate Hearing Loss

The introduction of OTC hearing aids act creates a new category in the hearing aids market that addresses the current limitations of the conventional hearing aids market. OTC hearing aids allows adults with mild to moderate hearing loss easy access to affordable hearing aids [30].

A hearing aid is a small electronic device worn in or behind the ear and used to improve hearing. These devices have three basic parts – a **microphone**, **amplifier**, and **speaker** – that pick up sounds, convert sounds waves to electrical signals, and send the signals to an amplifier.

The amplified sounds are detected by cells in the ear, which convert them into **neural signals** that are passed along to the brain. The amplifier sounds louder so that a person with hearing loss can hear more in both quiet and noisy situations. It allows them to communicate, engage, and participate more fully in daily activities and in social interactions.

Most people have mild to moderate hearing loss because of damage to the small sensory cells in the inner ear, called **hair cells**. This type of hearing loss is called **sensorineural hearing loss** [25]. *Figure 9* shows the anatomy of the ear with a detail of the hair cells contained in the cochlea. Mild hearing loss is defined by hearing deficits in the 26 – 40 dB range. It is experienced as difficulty or inability to hear soft noises and normal speech in a loud environment. Moderate hearing loss extends into the 41 – 71 dB range and impacts the ability to hear soft to moderately loud noise and to understand speech when any background noise is present [22].

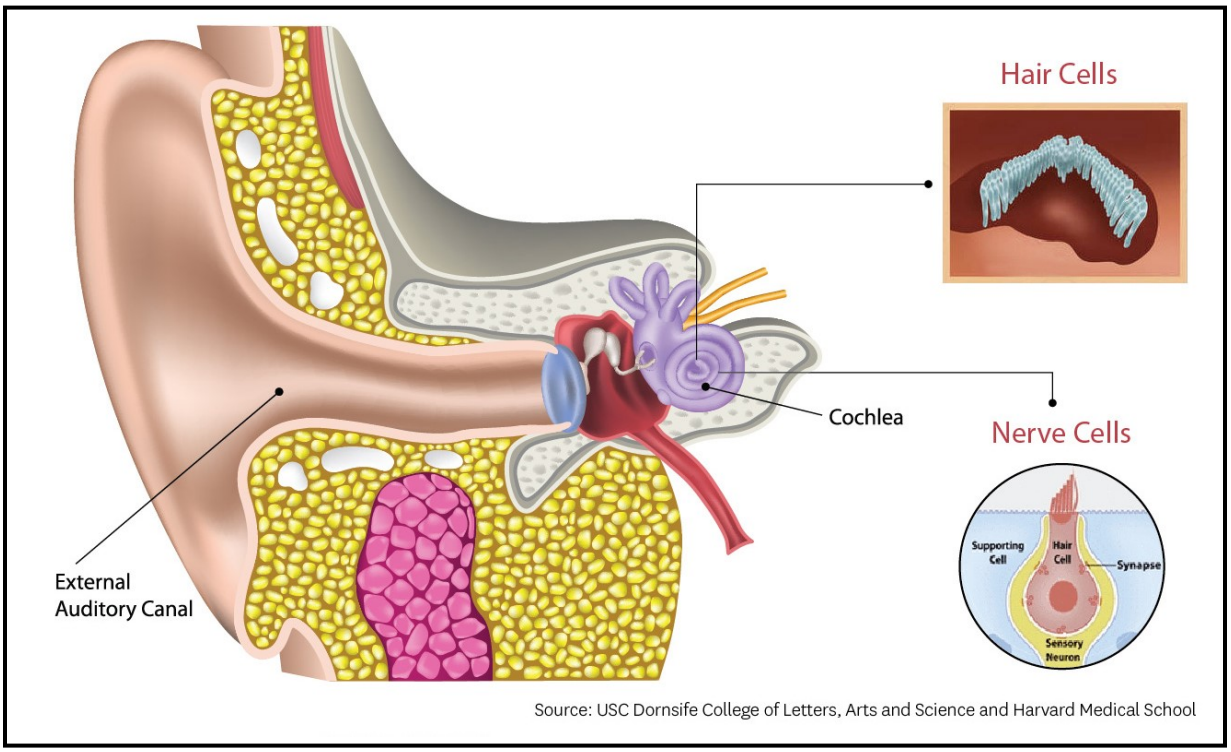

Figure 9. Anatomy of the ear

Different Types of Hearing Aids

Hearing aids are classified by the 4 different device placements: Behind-the-ear (BTE), in-the-ear (ITE), in-the-canal (ITC), and completely-in-canal (CIC). While both analog and digital hearing aids are available, digital devices dominate, accounting for USD 4.9 billion of the USD 5.3 billion market in 2018 [31].

Figure 10. BTE Hearing Aid

Source: Palm Coast Hearing Center

Figure 10 shows a behind-the-ear (BTE) hearing aid, which hooks over the top of the ear. A case for the battery compartment, microphone, and controls all rest behind the ear. A tube connects the device to a custom plastic ear mold that fits snuggly inside the outer ear and directs sound into the ear canal. This type of hearing aid is appropriate for those with mild to profound hearing loss [32].

Figure 11. ITE Hearing Aid

Source: Palm Coast Hearing Center

In-the-ear (ITE) hearing aids are small and sit in the outer portion of the ear canal with the housing completely filling the **concha**. *Figure 11* shows the shell of the hearing aid, which is custom-made to fit the shape of the ear. Depending on the size of the ear canal, the ITE hearing aid is relatively discreet. Advantages include a longer battery life, the availability of a power version for severe hearing loss, and improved operation [32].

Figure 12. ITC Hearing Aid

Source: Palm Coast Hearing Center

Figure 12 shows the in-the-canal (ITC) hearing aid, which is similar to a behind-the-ear hearing aid, with the speaker or receiver in the canal or in the ear. A tiny wire, rather than tubing, connects the pieces. It is custom-made to fit the size and shape of a person's ear canal. ITC hearing aids offer a secure fit, easy insertion and removal, and longer battery life. They work best for mild-to-moderate hearing loss [32].

Figure 13. CIC Hearing Aid

Source: Palm Coast Hearing Center

Figure 13 shows how CIC hearing aids fit completely in the ear canal making them the most discreet option. Like the ITC hearing aid, CIC are custom made for maximum comfort and sound quality. Because of their size, they don't offer some desirable features like volume control and a directional microphone. In addition, they use very small batteries that don't last as long as other options [32].

Hearing aids work differently depending on the electronics used. The two main types of electronics are analog and digital. *Figure 14* contrasts the different technologies. Analog devices only amplify

hearing in two channels – high-pitched sounds (treble) and low-pitched sounds (base). Digital hearing aids separate sound into numerous frequency bands. Each band can be adjusted, allowing for a more custom sound profile.

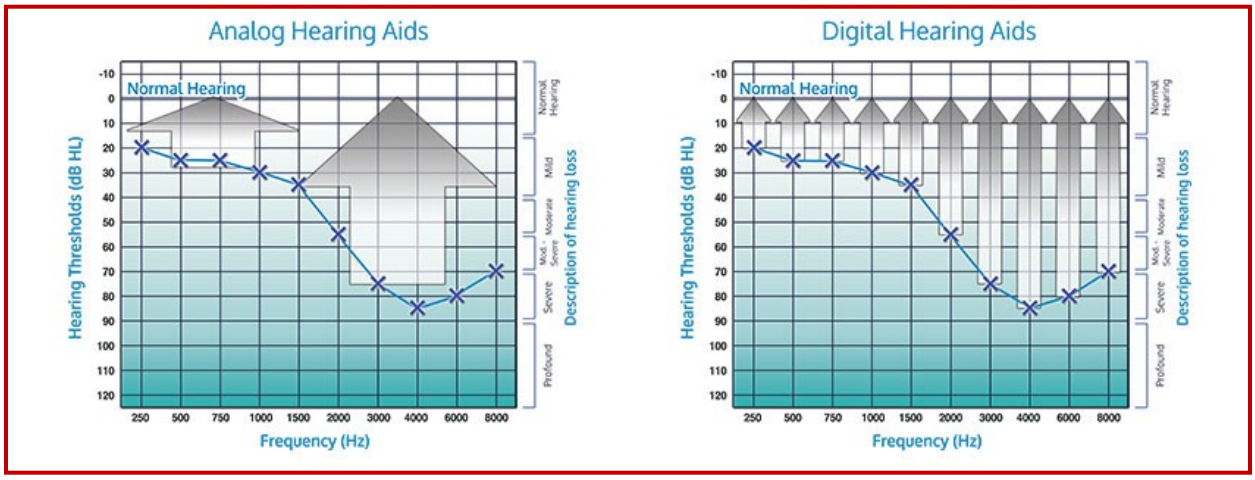

Figure 14. Analog vs Digital Sound Amplification Source: Hearclear Hearing Solutions

- **Analog** hearing aids convert sound waves into an electrical signal and then amplify the sound. Sounds are amplified uniformly. Analog aids usually are less expensive than digital aids [33].

- **Digital** aids convert sound waves into numerical codes. The amplifier is basically a small computer that can do more than just amplify sounds. Digital circuitry gives an audiologist greater flexibility to adjust the aid to a user's needs and fine tune the aid for a greater variety of listening environments. Digital aids offer vastly more features, including sound feedback cancellation, a directional microphone, noise management, and a host of connectivity options [33].

    - **Feedback Cancellation**: Digital hearing aids remove the feedback – the whistling sound emitted by analog hearing aids [33].

    - **Directional Microphones**: Directional microphones increase desired sound while decreasing undesired sounds. Digital hearing aids analyze the environment and turn on these microphones automatically [33].

    - **Noise Management**: This feature helps people hear better in a variety of environments. Noise management filters noise from

busy environments as well as background interference from the hum of an air conditioner, refrigerator, or computer fan [33].

- **Connectivity**: Digital hearing aids can wirelessly connect to many sound sources, including a cell phone, computer, tablet, television, and other media [33].

OTC Hearing Aids

OTC Hearing Aids Act of 2020

The *OTC Hearing Aid Act of 2017*, which was signed into law on August 24, 2017, will allow adults with perceived mild to moderate hearing loss access to OTC hearing aids. The FDA is currently establishing regulations for this law that must be provided by August of 2020 and finalized within 180 days thereafter [34].

The new law requires the FDA to create the OTC hearing aids category and regulate it to ensure:

- They meet the same high standards for safety, efficacy, labeling, and manufacturing that all medical devices must meet [34].
- They address requirements that OTC hearing aids sales be permitted in-person, by mail, and online by any adult over age 18 [34].
- They provide protections that prevent states from creating barriers to consumers that limit access to OTC hearing aids [34].

Hearables Operation as OTC Hearing Aids

Though the current main uses for hearables are communications, entertainment, fitness, and health coaching, their ability to deliver true hearing aid position them well to enter the hearing aid market through the emerging OTC hearing aids classification. Hearables are designed with components that provide improved hearing and comprehension for people

with mild to moderate hearing loss. Like conventional hearing aids, the AirPods Pro design includes an amplifier, speaker and microphone. *Figure 15* reveals additional components of the AirPods Pro, including a silicone tip, speaker driver, speech and motion sensors, and the new H1 chip, which benefit all listeners, including those with mild to moderate hearing loss, in the follow ways:

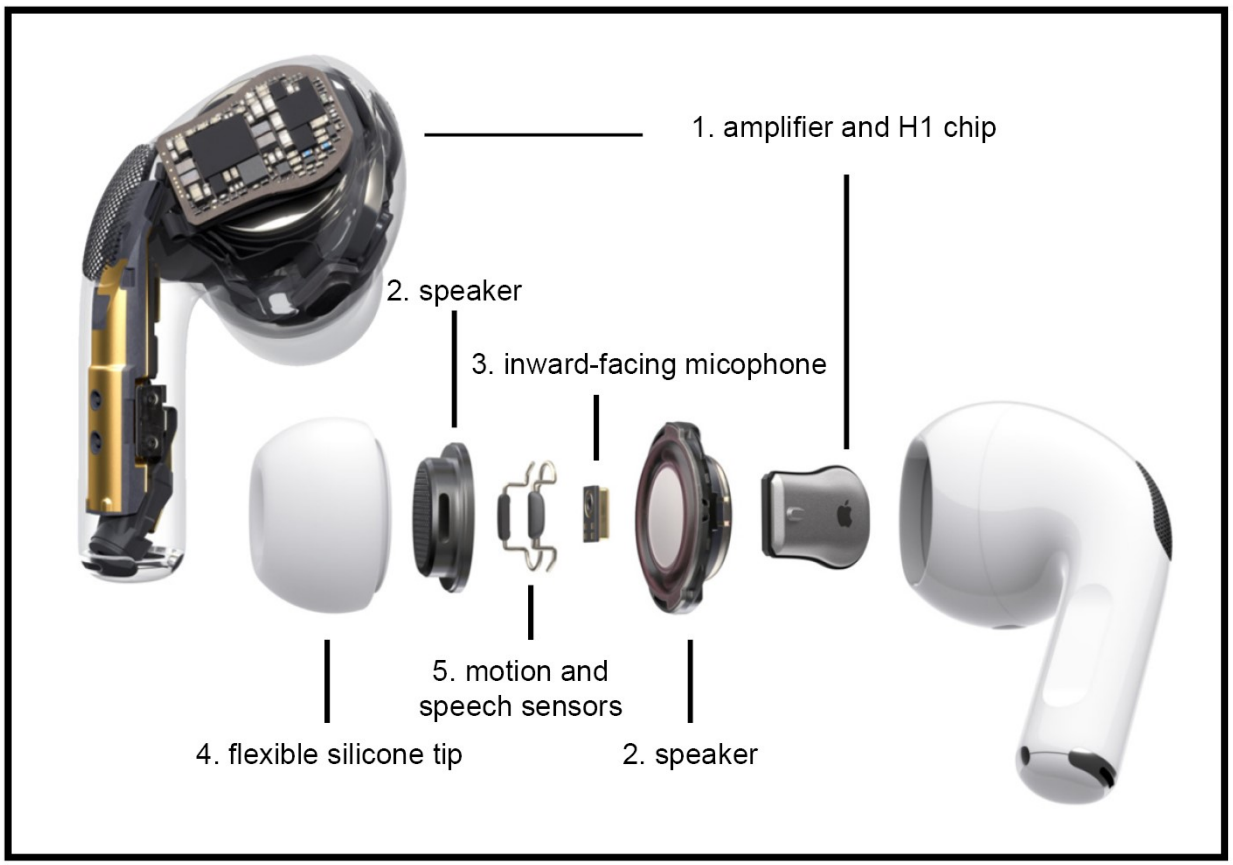

Figure 15. AirPods Pro Components Source: BGR

- **Amplifier & H1 Chip**: Apple created a custom-designed amplifier that captures the high **dynamic range** and produces clean, clear sound. Its enhanced efficiency extends battery life. The amplifier is connected to the system and powered by the Apple-designed H1 chip. The H1 chip also powers real-time noise cancellation, the **Adaptive EQ (equalizer)** feature, and connectivity features, including hands-free "Hey Siri" support [35].

- **Speakers**: The AirPods Pro speakers provide enhanced music and sound output. The custom high-excursion low-distortion speaker driver optimizes audio quality and removes background noise for improved bass and detailed mid and high frequencies. In addition, the adaptive EQ tunes the low and mid frequencies to the shape of the user's ear [35].

- **Inward-facing microphone**: The **inward-facing microphone** listens inside the ear for unwanted internal sounds. These sounds are factored into the speaker output by the speaker drivers. In addition, this microphone is an integral part of the active noise cancellation (ANC) technology [35].

- **Flexible silicone tip**: The AirPods Pro comes with 3 different sized tips to ensure a good seal in the ear canal. This seal is needed for the best ANC and for richer sound [35].

- **Motion and speech sensors**: The AirPods Pro has 2 **accelerometers** – the speech-detecting accelerometer works with the microphones to filter out external noise and focus on the sound of your voice; the motion-detecting accelerometer detects when the device is in the ear and will automatically pause the music when it is removed [35].

AirPods Pro OTC Hearing Aids Features and Functionality

Table 3, lists the features of the AirPods Pro and its functionality as an OTC hearing aid:

Table 3: Features and Functionality of AirPods as OTC Hearing Aids

Feature	Functionality
Active Noise Cancellation (ANC)	Uses 2 microphones – one outward-facing to capture unwanted external sounds, and one inward-facing to pick up unwanted internal sounds. The device produces anti-noise waveforms that cancel out the unwanted sounds resulting in enhanced incoming sound quality and speech.
Adaptive EQ	Tunes the low and mid sound frequencies to the shape of the shape of the listener's ear for an enhanced and cleaner listening experience.
Audio Transparency	Tones down ANC by letting more sounds in from the external environment so the listener can hear traffic, sirens, announcements, and other auditory cues.
Compatibility & Connectivity	Compatible with any device that supports Bluetooth. Will automatically connect and switch between multiple Apple devices.
Extended Battery Life	Operates 4.5 – 5 hours on a single charge. The carrying case will recharge the AirPods Pro in 15 minutes. The case holds enough charge to extend use to 24 hours.
Sweat Resistant	Water resistant with an Ingress Protection Code rating of IPX4 – protected from splashing water no matter the direction.
Touch Controls	The force center on the device stem lets the user play and pause music, skip a song, or answer a phone call.
Wind-proofed Microphone	Features expanded mesh that blocks the wind eliminating wind noise from the microphone.

Hearable OTC Hearing Aid Set-up and Use

OTC hearing aids will be supported by programs that allow the user to evaluate their hearing and customize their device. Online and electronic device applications allow individuals to test their hearing, adjust the fit of the device, and customize programs to fine tune the device. Results indicate these programs perform at levels equal to outcomes achieved by hearing care professionals [36].

- **Online hearing tests**: Traditionally, hearing care professionals perform a hearing test to get data points that are displayed in an

audiogram. An audiogram is a graph that shows how well an individual can hear a range of frequencies in a quiet environment. *Figure 16* shows a sample audiogram, where the vertical axis is sound intensity in **decibels (dB),** and the horizontal axis is sound frequency in hertz (Hz).

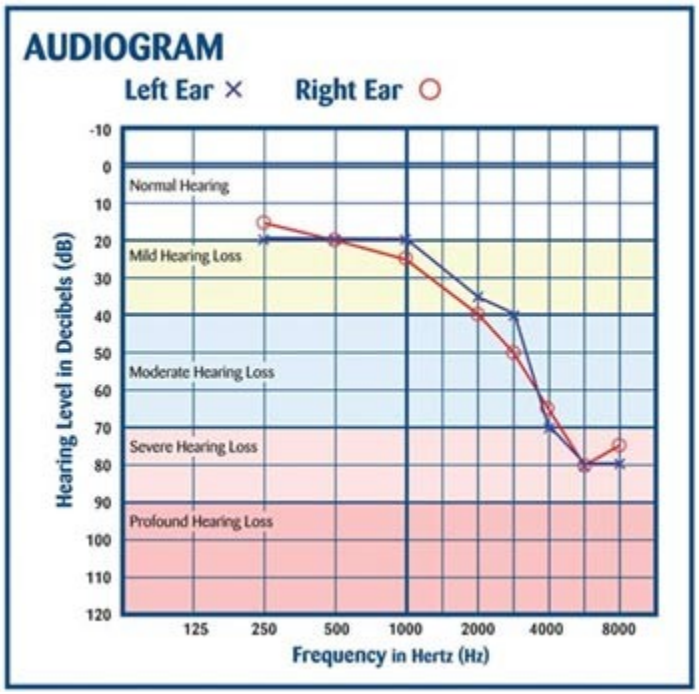

Figure 16. Audiogram Source: Hearing Industries Association

- At the top of the graph, 0 dB is the softest level of sound that a person with normal hearing can hear at any frequency. An adult that can hear between 0 – 25 dB has normal hearing. Sound frequencies, also called pitch, for speech are generally in the 250 – 6000 Hz range. Self-administered hearing tests are now available that provide accurate hearing threshold assessments can screen for mild or greater hearing loss [36].

- **Device customization applications**: Device customization applications allow the user to fine tune the OTC hearing aids to address their specific needs. In addition, the user can create programs or modes that allow optimal output for common settings. For example, the use might create one program for quiet setting, another program for conversations in a loud setting like a restaurant, a program for

outdoors where wind could be present, and a program for watching tv or talking on the phone [37].

The OTC Hearing Aid Act of 2017 stipulates that FDA regulations must include limits on device output to protect the user from sounds that could damage hair cells and negatively impact hearing [34]. While not mandated, device customization applications allow the user to maximize their benefit from using the OTC hearing aid and provide the user with higher rates of satisfaction [38].

Benefits of Hearables as OTC Hearing Aids

Benefits for Customers

The following table lists limitations of conventional hearing aids and shows the corresponding benefits of Hearables as OTC hearing aids options.

Table 4: Summary of OTC hearing aid customer benefits regarding conventional hearing aid limitations

Limitations of Conventional Hearing Aids	Hearables as OTC Hearing Aid Solution	Benefits Provided
High Initial Cost	Able to get OTC hearing aids at a fraction of the cost of conventional hearing aids.	✓ No testing fee ✓ No hearing care professional fee ✓ No prescription needed ✓ Affordable devices ✓ Can order devices in stores, online, or by phone
Large Time Investment	Able to get OTC hearing aids in a fraction of the time of conventional hearing aids.	✓ No testing required ✓ No doctors appointments ✓ No molds or impressions needed ✓ Sales are direct to the consumer ✓ Device adjustments, maintenance, and customer service available through online and retail store locations
Stigma	Look like earbuds and other hearables	✓ Reduces anxiety associated with looking old ✓ Removes barriers associated with ageism in professional and social settings ✓ User may address hearing loss sooner

Benefits for Other Stakeholders

The entry of hearables into the OTC hearing aids market classification also provides a number of benefits for current members of the hearing aids market:

Table 5: Summary of Hearables as OTC hearing aids benefits for the hearing aids market

Benefit	Description
Revenue generation	✓ Sales of AirPods-like OTC hearing aids product or products
Dominance in OTC hearing aids classification	✓ Expand reputation beyond electronics industry into hearing aids market ✓ Capitalize on hearables technologies that benefit individuals with mild to moderate hearing loss ✓ Utilize existing production and distribution channels to get devices in front of potential customers
Increased name recognition	✓ Grows the company's presence in the healthcare industry ✓ Opens opportunities to expand outside the electronics industry

Benefits for Apple

Hearables as OTC hearing aids will provide several benefits for Apple:

Table 6: Summary of Apple's benefits as an OTC hearing aid provider

Benefit	Description
Revenue generation	✓ Sales of AirPods-like OTC hearing aids product or products
Dominance in OTC hearing aids classification	✓ Expand reputation beyond electronics industry into hearing aids market ✓ Capitalize on hearables technologies that benefit individuals with mild to moderate hearing loss ✓ Utilize existing production and distribution channels to get devices in front of potential customers
Increased name recognition	✓ Grows the company's presence in the healthcare industry ✓ Opens opportunities to expand outside the electronics industry

Implementation Plan

Feasibility Assessment

Technical Feasibility

Apple is the global leader in the hearables market and has dominated sales with its AirPods wireless earbuds since their fall 2016 launch. When Apple added AirPods Pro with noise cancellation, **transparency mode**, and **live listen**, initial demand was greater than expected and both production and sales continue to increase.

Using its experience in the hearables market along with the insights and abilities gained through collaborations with hearing aid manufacturers, Apple can add an AirPods OTC into the AirPods family. Apple's yearly R&D spending has grown from $1 billion in 2009 to more than $15 million in 2019. It has invested in a range of technologies including wearables, augmented reality, artificial intelligence and more. While some additional research and development will be needed to design a product that meets the final regulations established by the FDA for OTC hearing aids, Apple already has a wealth of expertise from its earlier AirPods experiences.

Financial Feasibility

Since Apple’s product development team has run through the Apple new products process for earlier AirPods products, much of the design, engineering, and manufacturing is known. This knowledge and experience will reduce time and costs including salaries, materials, and operational costs. Apple’s AirPods products are expected to reach $175 billion this year.

Market Conditions

The OTC hearing aids act recommendations from the FDA are expected to be issued this summer and finalized in spring 2021. This change in the hearing aids market is the result of pressure and interest for an OTC hearing aids option. The low penetration rates of conventional hearing aids manufacturers among the 48 million Americans with mild to moderate hearing loss provide a compelling opportunity for Apple to destigmatize OTC hearing aids by providing a product that is indistinguishable from the status symbol that AirPods have become around the globe. In addition, the cost of an AirPods-like OTC hearing aid is a fraction of the cost of conventional options. Once AirPods OTC hearing aids are launched, high interest and sales are expected along with growing demand over the long term.

Recommendation

Apple is excellently positioned to bring to market a popular and desirable OTC hearing aid. Building on its hugely popular AirPods family of hearables products, Apple can continue to expand its reach outside of iPhone and Mac sales. With strong name recognition and a reputation for quality and simplicity, Apple will create trust and confidence in its OTC hearing aids and move into the familiar position of sales leader. Coordinating the launch of this product with the implementation of the OTC hearing aids act will allow Apple to take the lead in this new sector and maximize its position within it.

Resources Required

Apple possesses personnel within its product development teams to take the AirPods OTC through the Apple New Products Process (ANPP). The ANPP details every stage of the design process, defining with great detail every stage the teams will go through and when the product is expected to be completed. The following resources will be needed to develop and launch an AirPods OTC product:

Personnel:

- Project Team
  - 1 Design Lead
  - 1-2 Project Deputies
- The Industrial Design Studio Team
- Engineering Program Manager
- Global Supply Manager
- Product Development Launch Team

Figure 17 shows the hierarchy of this AirPods OTCC ANPP team.

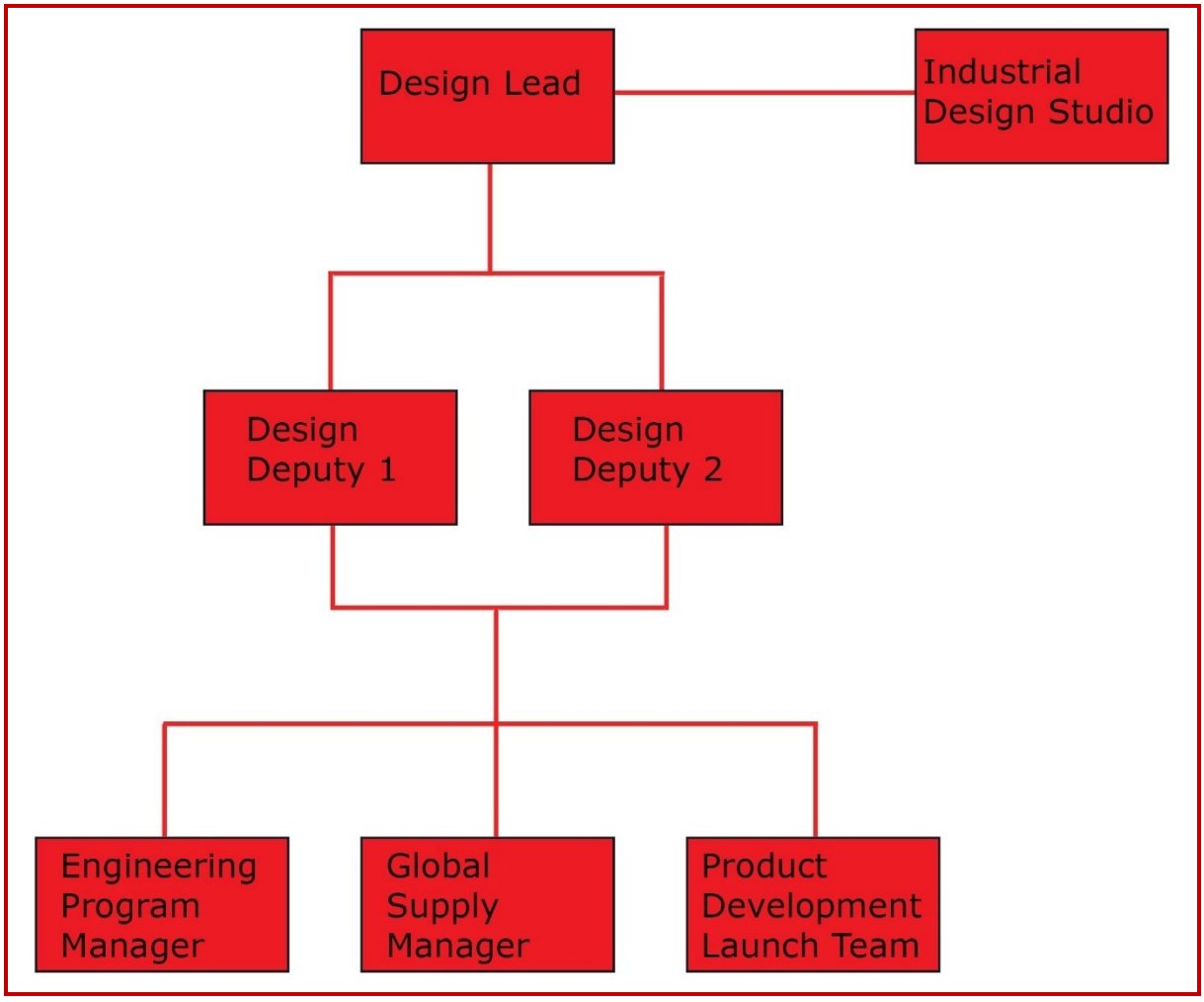

Figure 17. Hierarchy of AirPods OTC ANPP Management Team

Financial Considerations

The cost for Apple to enter the new OTC hearing aids market sector is likely to cost $70.5 billion the first year. See Table ? for more details.

- Salaries will account for $1.8 million annually.
- Manufacturing expenses account for $36 million annually.
- Advertising expenses will account for $32.5 million annually.

Time Frame

The estimated time needed to take the AirPods OTC project through the ANPP – from product design through production and launch – is 11 months.

Implementation Timeline

The AirPods OTC hearing aids project spans 11 months from the formation of the AirPods OTC new product team through full scale production and product launch. *Figure 18* shows the Apple New Product Process (ANPP) and the timeframe for each of the groups and tasks identified.

#	Task	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb
1	Form design teams											
2	Industrial Design Studio											
3	Design engineering											
4	Manufacturing design											
5	Evaluation & reengineering											
6	Marketing & advertising											
7	Full scale production											

Figure 18. AirPods OTC Implementation Timeline

Financials

Table 7 shows the annual expenses to Apple to add an AirPods OTC hearing aid to the AirPods truly wireless earbuds family.

Table 7: Outline of Apple's Required Expenditures for the AirPods OTC Project

Financial Application	Annual Cost (USD)
Personnel	
New Product Team	
Design Lead	190,000
Design Deputy 1	95,000
Design Deputy 2	95,000
Industrial Design Studio	975,000
Engineering Program Manager	55,000
Global Supply Manager	28,000
Product Development Launch Team	405,000
Subtotal	**1,843,000**
Marketing	
Advertising Campaign	32,000,000
Product Launch	500,000
Subtotal	**32,500,000**
Manufacturing	**36,000,000**
Total	**70,343,000**

Management

The AirPods OTC ANPP management team, which is responsible for all activities, research, and evaluations that resulted in the creation of this project and proposal, will provide executive oversight of the design team.

On the executive management team:

- Johny Srouji: senior vice president of Hardware Technologies
- Dan Riccio: senior vice president of Hardware Engineering
- Adrian Perica: vice president of Corporate Development
- Jodi Solomon: vice president of Wireless Technologies

Management Profiles

Johny Srouji

Senior Vice President of Hardware Technologies

Johny Srouji serves as senior vice president of Hardware Technologies at Apple, reporting to CEO Tim Cook. Johny has built one of the world's strongest and most innovative teams of silicon and technology engineers, overseeing breakthrough custom silicon and hardware technologies including batteries, application processors, storage controllers, sensors silicon, display silicon and other chipsets across Apple's entire product line.

Johny joined Apple in 2008 to lead development of the A4, the first Apple-designed system on a chip.

Prior to Apple, Johny held senior positions at Intel and IBM in the area of processor development and design.

Dan Riccio

Senior Vice President of Hardware Engineering

Dan Riccio is Apple's senior vice president of Hardware Engineering, reporting to CEO Tim Cook. Dan leads the Mac, iPhone, iPad and iPod engineering teams which have delivered dozens of breakthrough products.

Dan joined Apple in 1998 as vice president of Product Design and in 2010 was named vice president of iPad Hardware Engineering. Dan has been a key contributor to most of the company's hardware over his career and was instrumental in all of Apple's iPad products since the first generation iPad was introduced.

Prior to Apple, Dan worked at Compaq as senior manager of Mechanical Engineering where he was responsible for the mechanical design of Compaq's consumer PC products.

Adrian Perica

Vice President of Corporate Development

Adrian Perica is Apple's vice president of Corporate Development, reporting to CEO Tim Cook.

Adrian is responsible for the company's mergers, acquisitions and strategic investing efforts. Since joining Apple in 2009, he has overseen the successful integration of vital technologies and new businesses across hardware, software and services.

Prior to Apple, Adrian worked at Goldman Sachs for eight years and before that, he worked at Deloitte Consulting and was an officer in the US Army.

Jodi Solomon

Vice President of Wireless Technologies

Jodi Solomon is Apple's vice president of Wireless Technologies, reporting to CEO Tim Cook and COO Jeff Williams. Jodi provides leadership and coordination across Apple's product teams.

Jodi joined Apple in 2008, overseeing the development of cellular, Wi-Fi, Bluetooth, and location and motion technologies for nearly every Apple product. She also played a key role in developing the H1 chip for the AirPods 2 and AirPods Pro product lines.

Before joining Apple, Jodi served as vice president of Wireless Software Engineering at Palm and held key technical and managerial positions at other wireless companies.

Appendix: Glossary of Terms and Abbreviations

Term/Abbreviation	Description
1PX4	An IPX score is a rating to determine how water- or dust-resistant a product is. A 1PX4 rating indicates a product is resistant to water splashes from any direction.
acelerometers	A sensor that measures movement and vibrations.
active noise cancellation (ANC)	A method that reduces unwanted sound by adding a second sound specifically designed to cancel the first.
adaptive EQ	A feature of the AirPods pro that adjusts sounds to the shape of the ear.
ageism	Prejudice or discrimination based on a person's age.
AirPods	Truly wireless earbuds created by Apple.
AirPods Pro	Apple's next generation of AirPods featuring active noise cancellation, transparency mode, and a customizable fit.
amplifier	An electronic device for increasing the amplitude of electrical signals, used chiefly in sound reproduction.
analog	Audio reproduction that uses continuous vibrations to recreate the original sound waves.

Term/Abbreviation	Description
audio transparency	How well a reproduced sound matches the original.
audiological devices	Tools that help people with hearing impairment communicate better, such as hearing aids, cochlear implants, captioning, telephone amplifiers, and flashing and vibrating alarms.
baby boomers	People born in the years following World War II - 1946-1964 - when there was a temporary marked increase in the birth rate.
bass	The lowest part of the musical range.
big box store	A retail store that occupies an enormous amount of physical space and offers a variety of products to its customers. Examples include Walmart, Best Buy, and Lowe's.
Bluetooth	A standard for the short-range wireless interconnection of mobile phones, computers, and other electronic devices.
behind the ear (BTE)	A hearing aid that hooks over the top of your ear and rests behind the ear.
cardiovascular devices	Tools and equipment used to diagnose and treat heart disease and related health problems.
cochlear implants	A surgically implanted device that bypasses the normal acoustic hearing process and provides electric signals which directly stimulate the auditory nerve.

Term/Abbreviation	Description
compound annual growth rate (CAGR)	A business term for the return on investment over a period of time that measures a true return on an investment.
completely in the canal (CIC)	A hearing aid that fits completely inside the ear canal.
cognition	Conscious intellectual activity, such as thinking, reasoning, or remembering.
cognitive decline	Part of the normal aging process, cognitive decline is a response to the aging of neurons and the decreased speed at which the brain functions.
cognitively impaired	Decline in brain function that results in trouble remembering, learning new things, concentrating, or making decisions that affect their everyday life.
competitive advantages	Conditions or circumstances that put a company in a favorable or superior business position.
concentrated market	A market dominated by a few very large companies.
concha	The depression in the external ear leading to its central opening.
connectivity	The ability of a computer, program, device, or system to connect with one or more others.

Term/Abbreviation	Description
consolidated market	Term that describes and environment where a relatively low number of companies control a rather large share of the overall output or sales for a particular product or product type.
consolidation	The merger and acquisition of smaller companies in a market or industry into a few much larger ones.
consumables	Goods used by individuals and businesses that must be replaced regularly because they wear out or are used up.
conventional hearing aids market	A medical device designed to improve hearing by making sound audible to a person with hearing loss.
cool factor	An aesthetic of attitude, behavior, comportment, appearance, and style which cultivate admiration and approval.
decibels (dB)	A unit used to measure the intensity of a sound or the power level of an electrical signal by comparing it with a given level on a logarithmic scale.
dementia	A chronic or persistent disorder of the mental processes caused by brain disease or injury and marked by memory disorders, personality changes, and impaired reasoning.
depression	A mood disorder that causes a persistent feeling of sadness and loss of interest.

Term/Abbreviation	Description
diagnostic apparatus	Medical imaging machines used to aid in diagnosis, such as ultrasound and MRI machines, PET and CT scanners, and x-ray machines.
digital	A technology that is used to record, store, manipulate, generate and reproduce sound using audio signals that have been encoded in binary code.
directional microphone	A device designed to pick up sound from a particular direction while minimizing background sounds.
directional sound amplification	Hearing aid-like feature built into the AirPods Pro that amplifies desired sounds while minimizing background noise.
dynamic range	The span from the softest perceivable sound to the loudest.
electromagnetic compatibility	The ability of different electronic devices and components to work correctly in the presence of other devices that emit electromagnetic waves.
emerging economies	Nations that are investing in more productive capacity and moving away from their traditional economies that relied on agriculture and the export of raw materials.
FDA *de novo* status	An application sent by a medical device sponsor to FDA that establishes a new device type along with classification, regulation, necessary controls and product code.

Term/Abbreviation	Description
feedback cancellation	In hearing aids, feedback arises when a part of the receiver signal is captured by the hearing aid microphone, gets amplified in the device and starts to loop around through the system, resulting in a disturbingly loud tonal signal. Feedback cancellation is a technique that estimate the transmission path between loudspeaker and microphone(s). This estimate is then used to implement a neutralizing electronic feedback path that suppresses the tonal feedback signal.
feedback management systems	A feature in hearing aids used to achieve feedback cancellation.
frequency modulation (FM)	A wireless transmission method used to transmit sound that preserves the quality and clarity.
frequency	The speed of a vibration, which determines the pitch of a sound.
H1 chip	Next generation component for Apple’s AirPods 2 and AirPods Pro that handles fast pairing with Apple devices, maintaining the Bluetooth connection, "Hey Siri" support, and better-managed power for increased talk time.
hair cells	Sensory receptors of the auditory and vestibular systems in the ears.

Term/Abbreviation	Description
hearables	Smart headphones that are technically advanced, electronic in-ear-devices designed for multiple purposes ranging from wireless transmission to communication objectives, medical monitoring, and fitness tracking.
hearing specialist	There are two main types of hearing specialists: audiologists who have an advanced degree and instrument specialists who may only have an associate degree or high school diploma.
high-margin industry	Industry where sales less the cost of goods is high.
in the canal (ITC)	Hearing aids designed and sculptured to fit in the lower third of the external ear.
in the ear (ITE)	Hearing aids that sit in the outer portion of the ear canal and fit the shape of the ear.
intellectual property protections	Laws that safeguard companies' patents, copyright, industrial design rights, trademarks, plant variety rights, trade dress, geographical indications, and in some jurisdictions trade secrets.
isolation	A state of complete or near-complete lack of contact between an individual and society.
live listen	A feature of AirPods that lets an iPhone, iPad, or iPod touch act like a microphone that sends sound to your AirPods.

Term/Abbreviation	Description
market disruptor	An entity that creates a product, service, or way of doing things that displaces existing market leaders.
mature market	A market that has reached a state of equilibrium and has an absence of significant growth or a lack of innovation.
MedTech	Any devices, procedures, and systems developed to solve health problems and improve quality of life.
mergers and acquisitions (M&A)	Both mergers and acquisitions are a consolidation of companies. In a merger, two companies combine to form one, while with an acquisition, one company is taken over by the other.
microphone	An instrument for converting sound waves into electrical energy variations which may then be amplified, transmitted, or recorded.
neural signals	The electrochemical messages that neurons send to each other.
neuromodulation devices	Advanced medical tools that can enhance or suppress the activity of the nervous system.
noise emission	The sound emitted by a product independent of its location.
noise pollution	Any sound that is unwanted, is likely to irritate nearby individuals, cause distraction, cause hearing damage, or disrupts normal activities, and lowers quality of life.

Term/Abbreviation	Description
noise reduction systems	Hearing aid feature that eliminates unwanted noise by identifying the presence or absence of speech and enhancing that signal while diminishing the nonspeech signals.
oligopoly	A market structure in which a few firms dominate and have the power to set prices and limit competition.
over the counter (OTC)	Designation which indicated an item can be sold directly to a consumer without a license or a prescription from a healthcare professional.
personal sound amplification products (PSAPs)	Wearable electronic products that are intended to amplify sounds for normal hearing individuals.
research and development (R&D)	R&D represents the activities that companies undertake to innovate and introduce new products and services or to improve existing offerings.
receiver in the ear (RITE)	A hearing aid that places the speaker in the ear canal and the microphone and processor behind the ear.
regulatory framework	The laws, regulations, decrees and policies officially developed and approved by the government that enable it to use its coercive power to oversee products and services.

Term/Abbreviation	Description
self-fitting hearing aid	A wearable sound amplifying device that is intended to compensate for impaired hearing and incorporates technology, including software, that allows users to program the hearing aids themselves.
sensorineural hearing loss	Hearing loss resulting from damage to the hair cells in the inner ear or auditory nerve caused by noise exposure.
smart hearing aids	Devices that allow users to interact with their environment naturally while the device's algorithms sort out noise and enhance desired sound in real time.
speaker	A device that converts an electrical audio signal into a corresponding sound.
speech enhancement systems	Hearing aid feature that determines whether sound is noise or speech and then amplifies the speech sounds over the background noise.
status symbol	An object that signifies the owners' high social and economic standing.
stigma	A mark of disgrace that sets a person apart from others often resulting in negative perceptions, actions, and discrimination.
telecoil	A coil of wire in a hearing aid or cochlear implant that receives electromagnetic signals generated by audio induction loops which is then converted into sound.

Term/Abbreviation	Description
transparency mode	A feature of AirPods Pro that allows users with the option to simultaneously listen to music while still hearing the environment around them.
treble	Tones whose frequency or range is at the higher end of human hearing.
wearable technologies	Electronic hands-free devices, powered by microprocessors with the ability to send and receive data via the Internet that can be worn as accessories, embedded in clothing, implanted in the user's body, or even tattooed on the skin.
United States Food and Drug Administration (FDA)	A federal agency within the US Department of Health and Human Services responsible for protecting the public health by ensuring the safety, efficacy, and security of drugs, biological products, and medical devices; and by ensuring the safety of the nation's food supply, cosmetics, and products that emit radiation.

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