

# Medical Technology (MedTech) Industry Overview

---

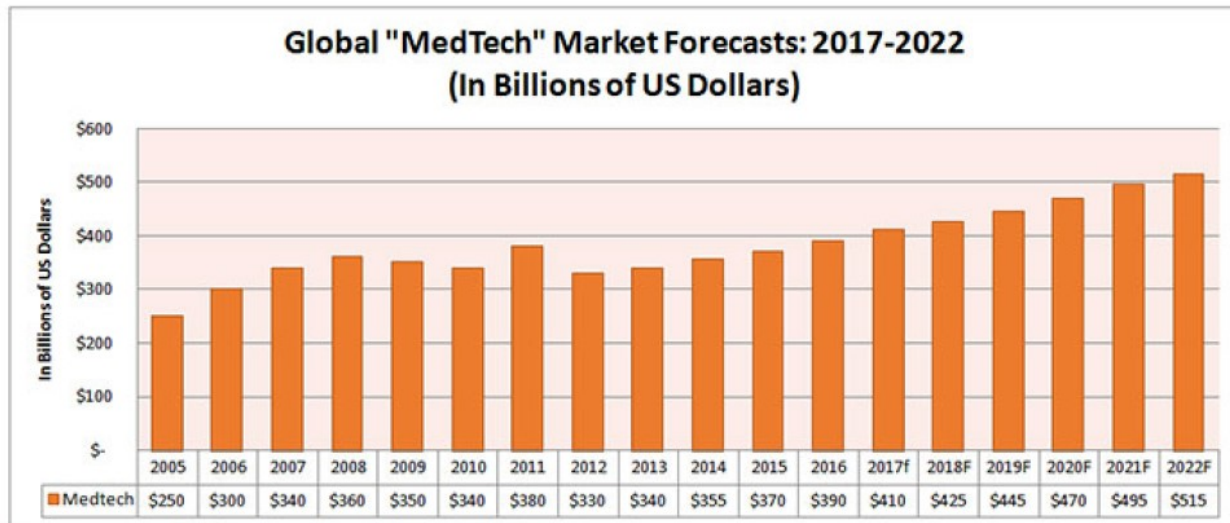
## Industry Profile

### Industry Description

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: Current and Historical

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 with a compound annual growth rate (CAGR) of 6% [4]. *Figure 1* illustrates historical and forecast growth of the industry from 2005 – 2022 [5].



Source: Paumanok Publications, Inc. In Billions of US Dollars

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].

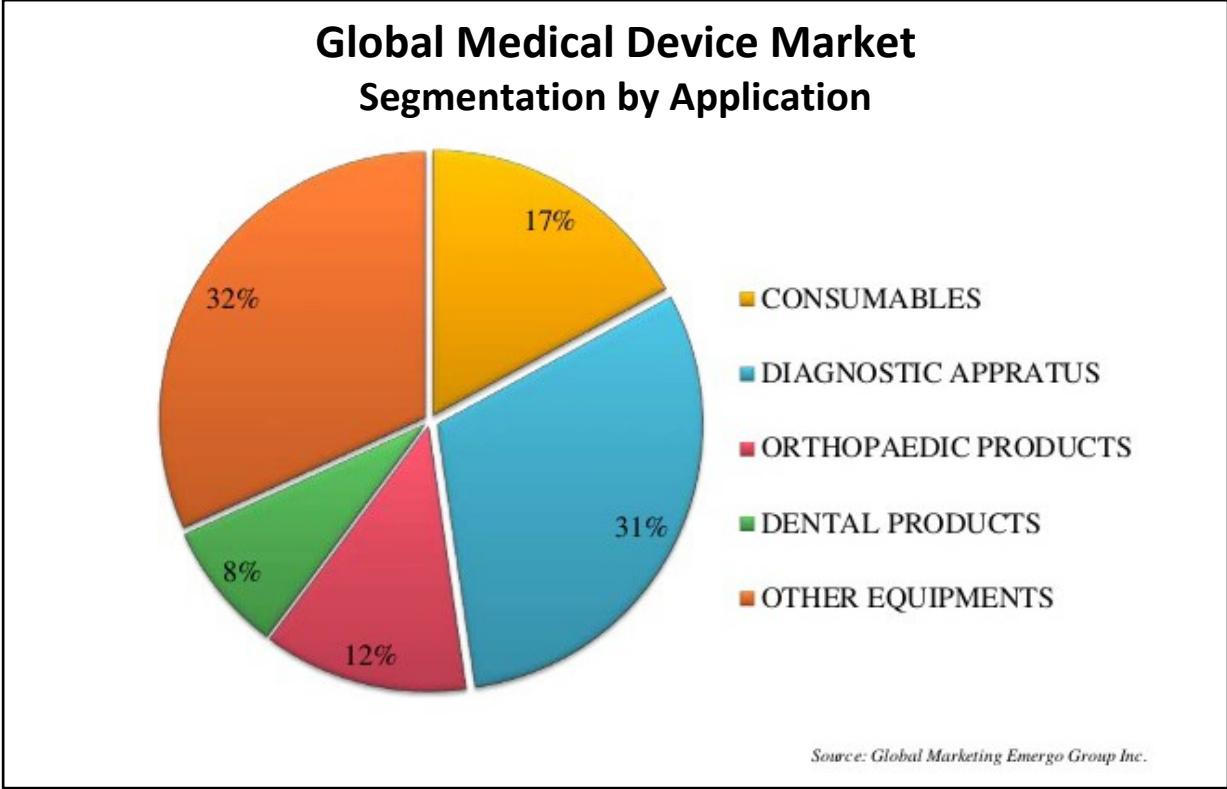


Figure 2: Global MedTech industry segmentation by product application: percent share to global revenue, 2019 [6].

### 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 percent 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.

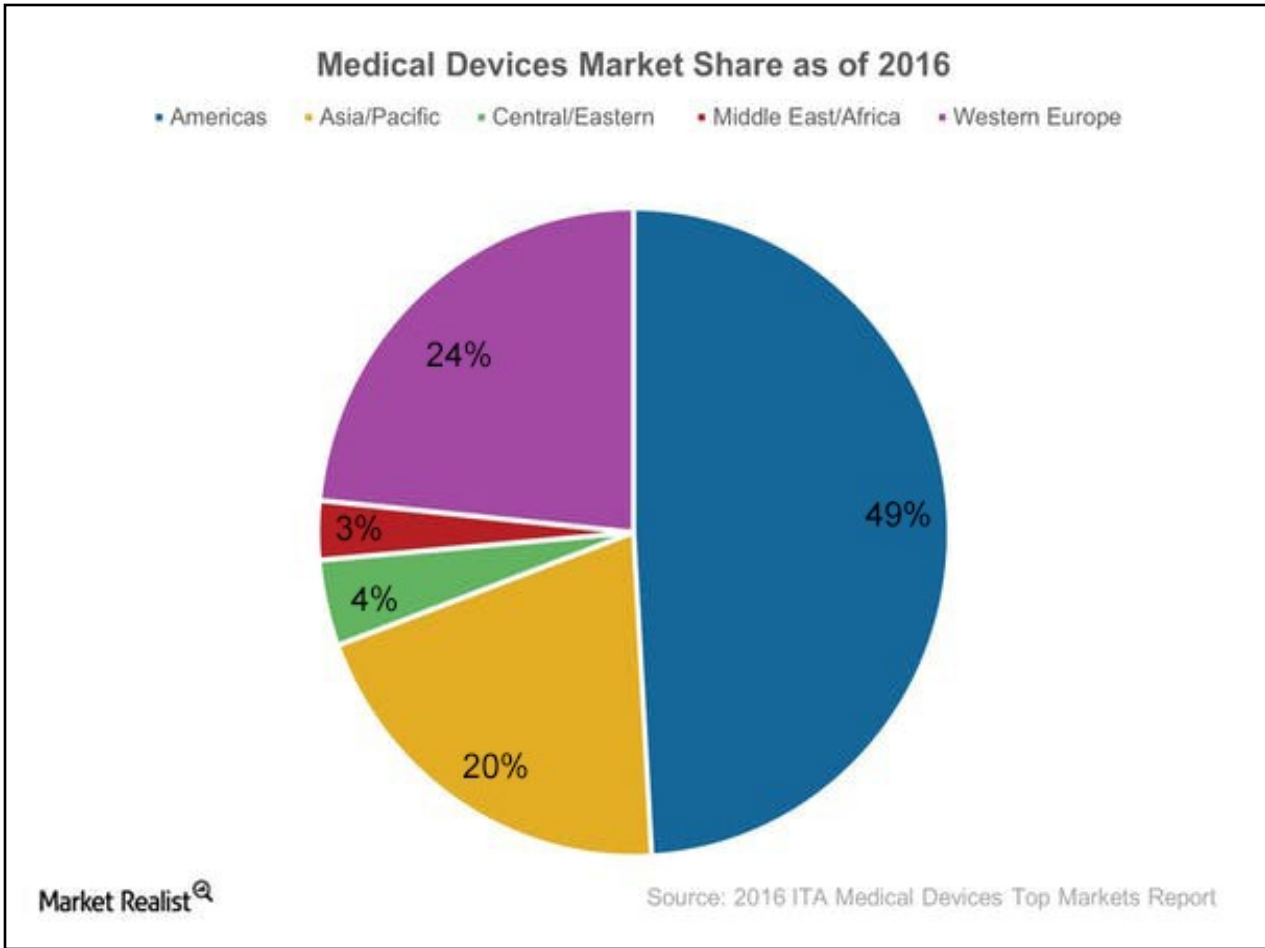


Figure 3: Global medical devices industry segmentation by geography: percent share contribution to global revenue, 2016 [7].

# 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:

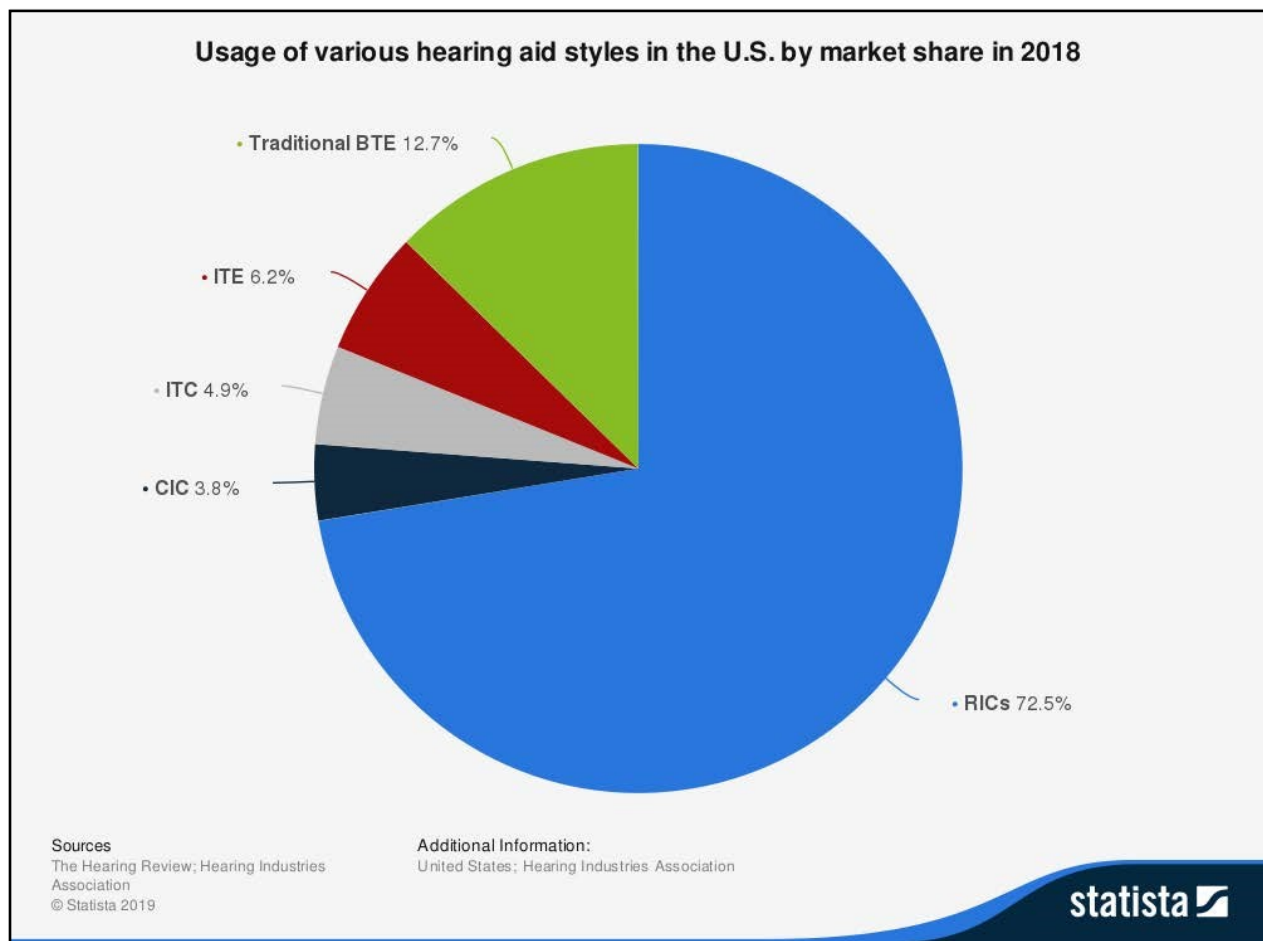


Figure 4: US hearing aids market segmentation by hearing aid type [9].

## 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:

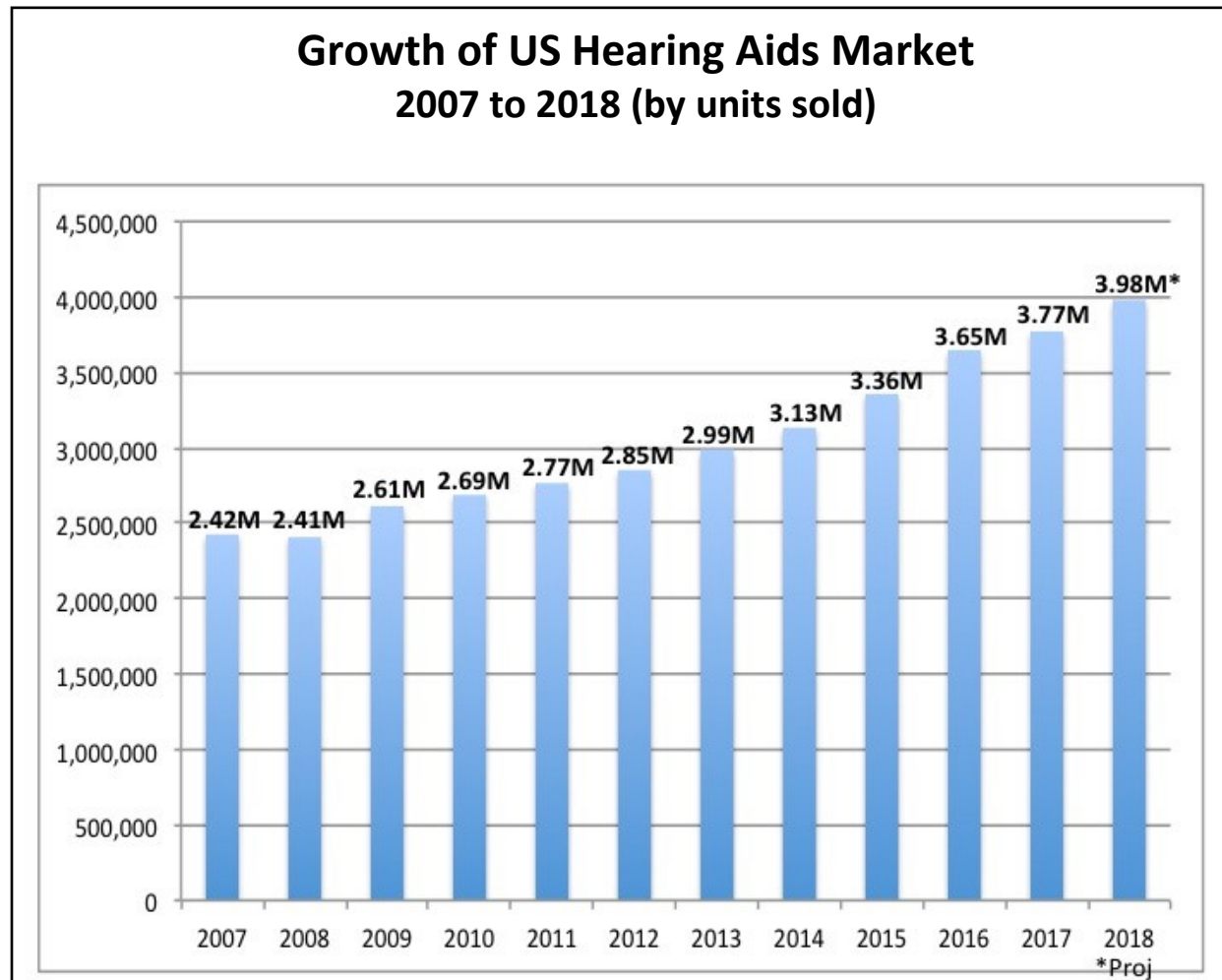


Figure 5: US hearing aid unit sales by year, 2007-2018 [11]. Source: The Hearing Review ([www.hearingreview.com](http://www.hearingreview.com))

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*).

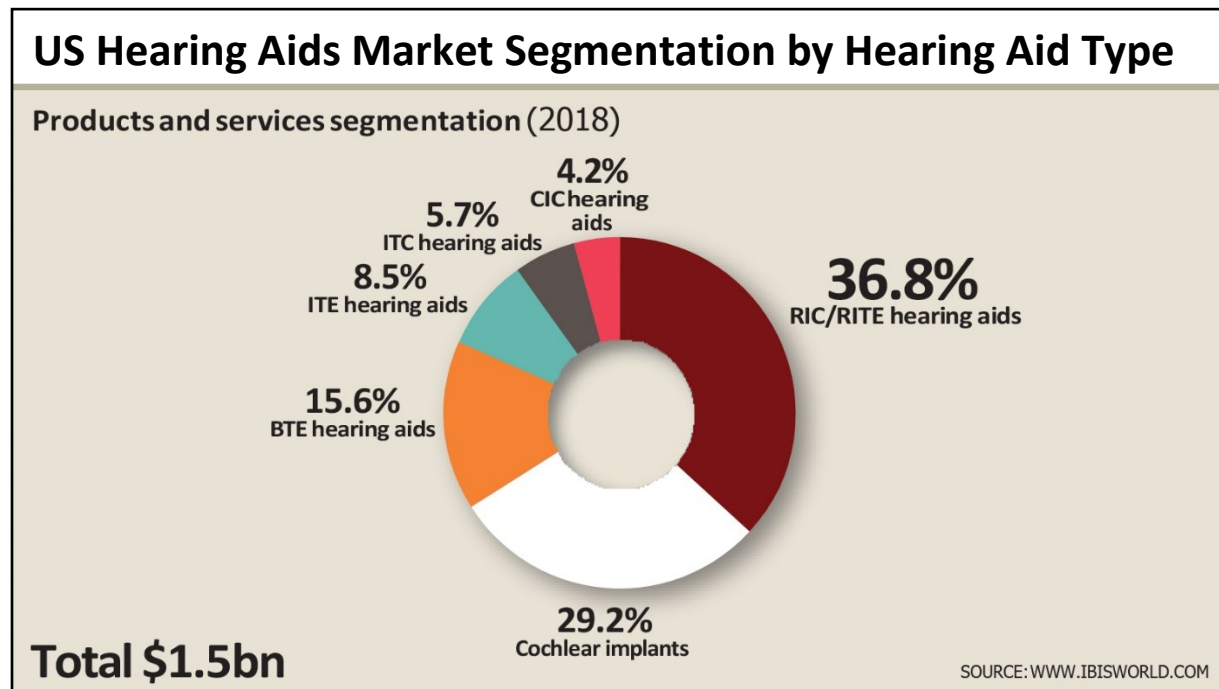


Figure 6: US Hearing Aids Market segmented by hearing aid type showing percent share of total revenue [8].

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.

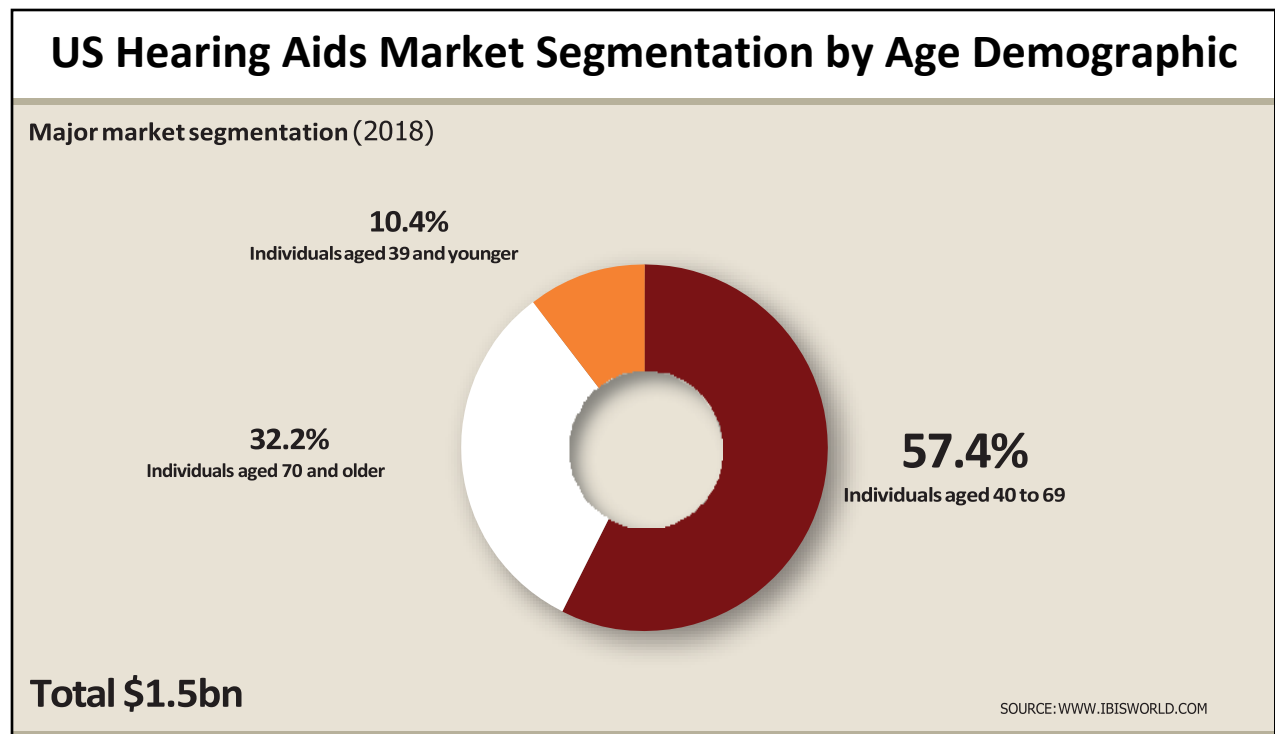


Figure 7: US Hearing Aids Market segmented by age showing percent share of total sales [8].

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 features:

- **Market dominated by major players:** In this consolidated market, the top 4 companies 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% 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.’ This 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.

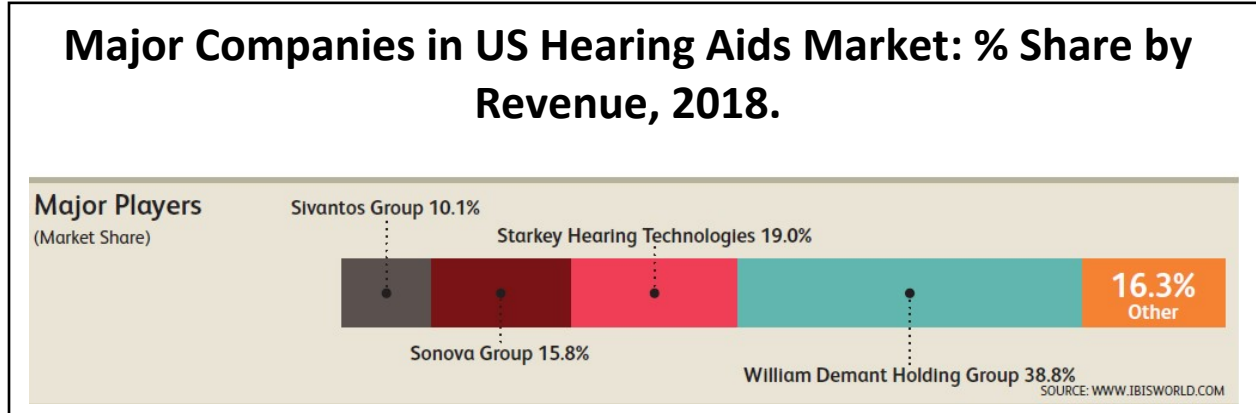


Figure 8: Major players in the hearing aid market: percent share by contribution to revenue, 2018 [13].

## 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%
<b>Total</b>	<b>31.8</b>	<b>100.0%</b>	<b>9.1</b>	<b>100.0%</b>	<b>250.0%</b>

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

## Competitive Advantages of Apple

Apple possesses several competitive advantages that may allow it to overcome the common obstacles that prevent many people with mild to moderate hearing loss from entering the market:

- **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.
- **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 to learn about and buy Apple products. In addition, Apple has already established retail stores around the globe for in-person sales and customer service assistance.
- **Cost.** With a pair of hearing aids averaging \$4,300, cost remains a significant barrier for many people living with hearing loss. Apple offers their AirPods and AirPods Pro for \$149 and \$249.

## Reference List

---

- [1] Mercer Capital. "Five Trends to Watch in the Medical Device Industry." Accessed on: Nov. 11, 2019. [Online]. Available: <https://mercercapital.com/article/five-trends-to-watch-in-the-medical-device-industry/>
- [2] Investment Bank. "Medical Device Manufacturing Executive Summary." Accessed on: Nov. 16, 2019. [Online]. Available: <https://investmentbank.com/med-device-manufacturing/>
- [3] "Medical Device Manufacturing in the US 33451B" IBISWorld (June 2019).
- [4] IQVIA. "The Rise of Global Medical Technology." Accessed on: Nov. 16, 2019. [Online]. Available: <https://iqvia.com/library/white-papers/the-rise-of-global-medical-technology>
- [5] TTI, Inc. "The Global Market for Medical Electronics and Outlook to 2022." Accessed on: Nov. 14, 2019. [Online]. Available: <https://www.tti.com/content/ttii/en/marketeye/articles/categories/passives/me-zogbi-20170228.html>
- [6] Emergo. "2019 Outlook for the Medical Device Industry." Accessed on: Nov. 11, 2019. [Online]. Available: <https://www.emergobyul.com/resources/2019-outlook-medical-device-industry>
- [7] Market Realist. "A Must-Read Overview of the Medical Device Industry." Accessed on: Nov. 11, 2019. [Online]. Available: <https://marketrealist.com/2016/11/must-read-overview-medical-device-industry/>
- [8] "Hearing Aid Manufacturing in the US: OD4068." IBISWorld (September 2018).
- [9] Statista. "Usage of various hearing aid styles in the US by market share in 2018." Accessed on: Nov. 24, 2019. [Online]. Available: <https://www.statista.com/statistics/664453/different-hearing-aida-used-by-the-market-in-us/>
- [10] The Hearing Review. "US Hearing Aid Sales Increase 5.3 % in 2018: Approach 4-Million Unit Mark." Accessed on: Nov. 21, 2019. [Online]. Available: <https://www.hearingreview.com/practice-building/us-hearing-aid-sales-increase-5-3-2018-approaches-4-million-unit-mark>
- [11] The Hearing Review. "Will Hearing Aid Sales Top 4 Million in 2018?" Accessed on: Nov. 21, 2019. [Online]. Available: <https://www.hearingreview.com/hearing-loss/hearing-loss-prevention/industrial-military/will-hearing-aid-sales-top-4-million-units-2018>
- [12] Mordor Intelligence. "Hearing Aids Market –Growth, Trends, and Forecast 2019-2024." Accessed on: Nov. 21, 2019. [Online]. Available: <https://www.mordorintelligence.com/industry-reports/hearing-aids-market>

[13] US Department of Health & Human Services, National Institutes of Health, National Institute on Deafness and Other Communication Disorders. "Age-Related Hearing Loss." [Online]. Available: <https://www.nidcd.nih.gov/health/age-related-hearing-loss>

[14] World Health Organization. "Deafness and Hearing Loss." Accessed on: Nov. 21, 2019. [Online]. Available: <https://www.who.int/en/news-room/fact-sheets/detail/deafness-and-hearing-loss>

[15] The Hearing Review. "Biosensors in Hearing Aids: Technology to Enable Daily Healthcare Through Hearables." [Online]. Accessed on: Nov. 24, 2019. Available: <https://www.hearingreview.com/practice-building/practice-management/continuing-education/biosensors-hearing-aids-technology-enable-daily-healthcare-hearables>

[16] The Hearing Review. "Survival Strategies in a Competitive Hearing Healthcare Market." Accessed on: Nov. 21, 2019. [Online]. Available: <https://www.hearingreview.com/practice-building/survival-strategies-competitive-hearing-healthcare-market>

[17] US Department of Health & Human Services, National Institutes of Health. "Self-Fitting Hearing Aids: Status Quo and Future Predictions." [Online]. Available: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4871211>

[18] The Hearing Review. "ADA's 40<sup>th</sup> Convention Prepares Members for Disruption and OTC Devices." Accessed on: Dec 5, 2019. [Online]. Available: <https://www.hearingreview.com/practice-building/practice-management/medicare-insurance/adas-40th-convention-prepares-members-disruption-otc-devices>

[19] "Hearables." <https://en.wikipedia.org/wiki/hearables>

[20] Gadgets & Wearables Health and Fitness. "Hearables drive wearables growth in Q2 2019." Accessed on: Dec. 5, 2019. [Online]. Available: <https://gadgetsandwearables.com/2019/09/10/hearables-2019/>