Hearing aids as medical devices and their new declassification opportunities

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Reading time 10 mins

Key Points

- The World Health Organization’s prediction that one in every 10 people will require

some form of hearing rehabilitation by 2050 has led to a worldwide focus on reducing deafness

- The global market for hearing aids is forecast to grow from USD 10.1 billion in 2021 to USD 15.5 billion by 2030
- The FDA's declassification of hearing aids as medical devices (for mild to moderate hearing loss) allows them to now be sold over-the-counter (OTC) in the USA which increases competition, promotes innovation, and greatly reduces the costs to consumers
- In the UK, hearing aids are available for free with the NHS and also available OTC – although options are limited. Declassification in the US creates more options for UK consumers and product developers
- The market is highly driven by technology and allows direct-to-consumer hearing aid companies to integrate personalised features (e.g. online hearing tests developed by audiologists, remote aftercare, tech support, and smartphone app synchronisation to tweak settings) that weren't available before

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The World Health Organization (WHO) estimates that by 2050, almost 2.5 billion people will experience some form of hearing loss [1] and that approximately 700 million people (i.e. one in every 10) will require hearing rehabilitation. The classification of hearing aids as medical devices (or not) is pertinent as it affects access, costs, and the regulations placed on them – which, depending on restrictions, can either cultivate or cripple innovation and development.

In August 2022, the Food and Drug Administration (FDA) finalised a historic rule to enable millions of Americans to access over-the-counter (OTC) hearing aids. The declassification of hearing aids as medical devices will [2]:

- Allow consumers with mild to moderate hearing loss to purchase hearing aids online or directly from retailers without needing a medical exam, prescription, or fitting by an audiologist
- Lower the cost of hearing aids
- Improve access to high-quality healthcare
- Foster innovation and competition in the hearing aid technology marketplace
- Continue to be regulated by the FDA to ensure that devices maintain standards of safety and effectiveness

How does hearing aid classification affect UK consumers and developers?

This declassification was needful in an American context, where health coverage is significantly different than in the UK. In the US, hearing aids aren't covered by most insurance companies or Medicare (a government national insurance program). The global market for hearing aids was valued at USD 10.1 billion in 2021 and dominated by just 6 companies. This meant there wasn't much competition and led to costs of up to USD 4,000 – USD 7,000 for hearing aids – which consumers paid for out of their own pockets [3]. Declassification could see prices drop to less than USD1,000 by mid-2023.

This isn't the case in the UK, where hearing aids are still classified as Class IIa medical devices (medium to low risk) and regulated by the Medicines and Healthcare products Regulatory Agency (MHRA). Hearing aids are available on the NHS and over the counter due to this classification. The benefits are that hearing aids as medical devices provided by the NHS are free, as are the batteries and repairs. In addition, users don't have to pay for follow-up appointments or aftercare.

On the other hand, the waiting time for treatments with the NHS can take longer than for private treatment. In addition, they only pay for Receiver In the Ear (RITE) or Behind the Ear (BTE) devices, so people who prefer other types would have to do so privately. For example, Invisible in the Canal (IIC) and Completely In the Canal (CIC) devices.

Pros and Cons of OTC hearing aids for users

Regardless of whether people are based in countries where they have access to a free – but limited – range of hearing aids or countries where the only choice is how much they're able/willing to pay, OTC hearing aids could be an ideal middle ground.

OTC devices are not designed for people with severe or chronic hearing loss. They are also known as Assisted Listening Devices (ALD), Personal Sound Amplification Products (PSAP), off-the-shelf hearing aids, and hearables. The main benefits of these devices are cost and accessibility, as people can expect to pay between £99 to £500 per device.

The main disadvantages cited by organisations such as Hearing Aid UK are: users don't consult with an audiologist before purchasing and often don't receive any aftercare or technical assistance once the device is bought. This can lead to damage to the user's ears due to over-amplification since OTC hearing aids aren't personalised to suit the individual's level of hearing loss.

However, Jabra Enhance (an online hearing and direct-to-consumer business) illustrates that this doesn't have to be the case:

- High-tech hearing aids that are discreet and comfortable
- Costs from £1,000 with 100 days free trial
- Users first take a hearing test developed by audiologists online
- Devices are then programmed depending on the user's test results
- 3 years of follow-up care with audiologists (remotely)
- Technical support is available 7 days a week
- 3-year warranty that covers manufacturer defects, loss, and damage
- Bluetooth enabled
- The smartphone app allows for further customisation and enables their team of audiologists to tweak settings remotely

Other concerns regarding the effectiveness of OTC hearing aids as medical devices (or not, depending on the country where users are based) include [4]:

- They cannot treat severe hearing loss or impairment associated with injury or an

underlying medical condition
- Devices need to be self-fitted, so they cannot be customised for the user's ear
- They may come with shorter warranties than prescription devices

Do OTC hearing aids as medical devices create opportunities for developers?

The declassification of hearing aids as medical devices is good news for product developers and customers worldwide. UK-based customers will have a global selection from which to purchase, while developers will benefit from a larger target market.

Indeed, when looking at the global hearing aid market, growth is forecast at a steady compound annual growth rate (CAGR) of 4.5%, which could reach up to USD 15.5 billion by 2030 [5]. The report, conducted by Grand View Research, found that there is also:

- Growing awareness regarding the benefits of technologically enhanced devices as a treatment for hearing impairment
- Longer life expectancies are leading to a growing senior population who have a greater tendency to suffer from hearing impairment

- Increased innovation has led to the emergence of novel products such as the world's first waterproof rechargeable hearing aid (resistant to fresh, pool, and salt water up to 50cm) and AI-enhanced hearing aids
- Healthcare infrastructure in emerging economies that is undergoing rapid development creates space for the implementation of new technologies
- A global focus on reducing deafness has led to the introduction of various initiatives, government subsidies, and more funding opportunities

A market that is highly driven by technology and one where subsidies and funding are more available is even better news for developers. It confirms that there is a demand for both hearing aids as medical devices – and hearables that significantly improve the quality of life for people suffering from 'normal' hearing loss as they age. A demand that developers and creatives motivated by human-centred design and multi-disciplinary collaboration are best suited to fill.

We've got our ear to the ground…

At Ignitec, we take pride in staying abreast of the latest news and developments, particularly where healthcare and sustainability are concerned. The FDA's declassification of hearing aids as medical devices was certainly music to our ears as we could see how this would be a game-changer for users and developers worldwide.

The MHRA is currently revising regulations regarding UK medical devices, and we're interested to see how this will promote further innovation and collaboration between diverse industries – while avoiding the pitfalls of big data. Are you as curious as we are? Signup for our newsletter, and we'll keep you tuned into what's new and trending.

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