



# ASX Announcement

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## NUHEARA SUBMITS 510(k) FOR U.S. FDA CLEARANCE

Nuheara Limited (**ASX:NUH**) (**Company** or **Nuheara**) has taken the final step in its plans to secure US Food and Drug Administration (**FDA**) clearance for its self-fitting hearing aid by providing its 510(k) submission to the FDA.

This follows completion of Nuheara's successful clinical trial by National Acoustic Laboratories (**NAL**) in January 2022. The trial successfully validated the effectiveness of the Nuheara self-fitted hearing aids compared to unaided listening across a range of settings and situations.

The Nuheara hearing aids are designed to be self-fitted by the user, with a software application interface for both iOS and Android smartphones, intended for direct-to-consumer sale and use without the assistance of a hearing care professional. They are intended for individuals 18 years of age or older with perceived mild to moderate hearing loss, which makes up 85% of the US market.

The FDA submission for clearance is the final step of Nuheara's expansion plans into the regulatory approved medical device market, which also aligns with the much-awaited U.S. Over-The-Counter Hearing Aid final rule publication in the Federal Register by the FDA expected for northern hemisphere mid-summer 2022.

Co-founder, Managing Director & CEO Justin Miller said: "Over the last seven years Nuheara has shifted its focus from being a consumer electronics hearables company to driving an entirely new market in medical device technology with its self-fitting hearing aids.

"Our ambition to enter the US regulated medical device market has been pursued tirelessly by the Nuheara team and their commitment is evidenced by the sheer fact Nuheara embarked on this 510(k) journey only 12 months ago.

"This submission could not have been achieved without all the progress we made in pioneering hearable products to underserved customers in the global hearing market. This was supported by decisions we made along the way to clinically validate our proprietary technology such as Ear ID™.

“Once FDA clears our submission, we will have overcome the three major barriers to entering the hearing aid market. These are, world leading hearing product & technology, alternative non-traditional paths to distribution, and lastly meeting strict regulatory standards.

“Creating and manufacturing self-fit hearing aid technology that is clinically validated to perform as effective as a professionally fit hearing aid has been a feat which incumbent hearing aid companies have not yet proven. Nuheara’s in-market innovation has been building towards this for five years.”

Chief Revenue Officer and President Americas, John R. Luna, stated: “Nuheara’s submission sets the foundation to expand Nuheara’s footprint in the U.S. and globally in the regulated medical device markets.

“Positioning Nuheara’s self-fit hearing aid with FDA regulatory clearance now will enable us to take full advantage of the 800.30 US FDA Over the Counter market opening expected later this year.

“Our year-on-year growth which has been established through our Direct-to-Consumer and omnichannel approach will also support stronger gains in our mainstream retail partnerships, once cleared, then growth opportunities with our hearable partners will extend to our OTC hearing aid.

“Nuheara is prioritising its marketing initiatives in the US to ensure that these growth opportunities will be capitalised upon in the short-term.”

Clinical trial summary of Nuheara’s self-fit hearing aid by National Acoustic Laboratories (NAL)

- Clinical assessment showed improvement in speech understanding by 30% in noise when the Nuheara IQbuds™ 2 PRO hearing aids FOCUS feature was enabled.
  - This outcome is consistent with industry standard clinical studies showing speech understanding in noise advantages with conventional directional microphones in hearing aids ranging from 25% to 30%, depending on the familiarity to the speech, physical fitting and design of the hearing aids (Ricketts, 2001<sup>1</sup>; Keidser et al., 2013<sup>2</sup>)
- Substantial evidence of the benefit of the Nuheara IQbuds™ 2 PRO self-fitted hearing aids compared to unaided listening with the following benefits:
  - Improved speech understanding in noise
  - Improved ability to follow conversations
  - Ability to reduce background noise levels
  - Overall frequent improvement when listening in everyday conversations
- Clinical performance of self-fitting IQbuds™ Ear ID™ software found effective

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<sup>1</sup> Ricketts TA. Directional Hearing Aids. Trends in Amplification. 2001;5(4):139-176. doi:[10.1177/108471380100500401](https://doi.org/10.1177/108471380100500401)

<sup>2</sup> Keidser G, Dillon H, Convery E, Mejia J. Factors influencing individual variation in perceptual directional microphone benefit. J Am Acad Audiol. 2013 Nov-Dec;24(10):955-68. doi: 10.3766/jaaa.24.10.7. PMID: 24384081

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**ABOUT NUHEARA**

Nuheara is a global leader in smart hearing technology which change people's lives by enhancing the power to hear. As a global pioneer in Hearable products, Nuheara developed proprietary, multi-functional, personalised intelligent hearing devices that augments a person's hearing. Nuheara is headquartered in Perth, Australia and was the first consumer wearables technology company to be listed on the Australian Stock Exchange (ASX).

In 2016, the Company released its revolutionary wireless earbuds, IQbuds, which allow consumers to augment their hearing according to their personal hearing preferences and connect hands free with their voice-enabled smart devices. In 2020 Nuheara released its third-generation hearable the IQbuds<sup>2</sup> MAX. In 2021, Nuheara transformed its operations to include medical device manufacturing for its hearing aid products to meet global demand for mild to moderate hearing loss. In 2022, Nuheara established its U.S. headquarters in Bellevue, Washington. Nuheara products are now sold Direct to Consumer (DTC) and in major consumer electronics retailers, professional hearing clinics, pharmacies and speciality retailers around the world.

The Company's mission is to transform the way people hear by creating smart hearing solutions that are both accessible and affordable. For further information, please visit <https://www.nuheara.com/>.