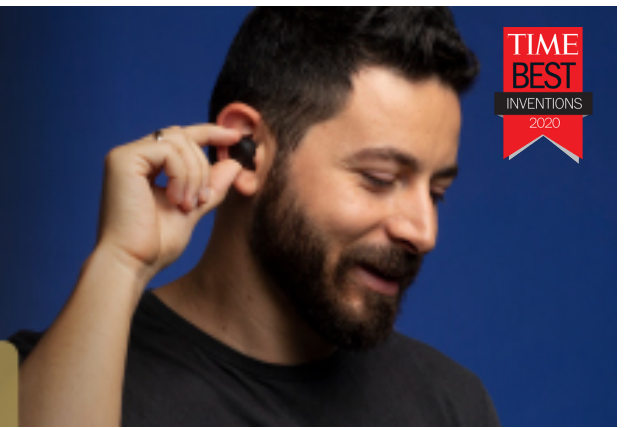


ASX Announcement

Release Date: 31 OCTOBER 2022



NUHEARA RECEIVES HISTORIC FDA CLEARANCE FOR SELF-FITTING OTC HEARING AID AND LAUNCHES HP HEARING PRO

Highlights

- Nuheara has received an historic and first of its kind FDA 510(k) premarket clearance for both an 874.3325 Self-fitting Hearing Aid and the 800.30 Over The Counter (OTC) hearing aid classification
- A notable clearance for what is termed as a “Self-Fitting Air-Conduction Hearing Aid, Over The Counter” with the unique product code “QUH”
- Nuheara plans to launch its Self-Fitting OTC Hearing Aid as the **HP Hearing PRO**
- HP Hearing PRO Self-Fitting OTC Hearing Aid Hearing Aids include the following clinically validated¹ features:
 1. 30% improvement in speech in noise with the use of Focus directional microphones
 2. Self-Fitting with Ear ID™ proprietary software via the HP Hearing mobile application
 3. Improved ability to follow conversations and reduce background noise
 4. Clinically validated, natural sound quality

PERTH, AUSTRALIA: Medical device and consumer electronics manufacturer, Nuheara Limited (**ASX:NUH**) (**Company** or **Nuheara**) is pleased to announce a major milestone, receiving US Food and Drug Administration (FDA) clearance for its Self-Fitting OTC Hearing Aid. Nuheara’s **HP Hearing PRO** has been cleared by the FDA for both 874.3325 self-fitting and the 800.30 OTC hearing aid classifications under a new product classification code “QUH”.

Following the landmark law establishing a regulatory category for over-the-counter (OTC) Hearing Aids in the United States (enacted on 17 October 2022) Nuheara plans to bring to market its first medical device as the HP Hearing PRO under its worldwide Trademark License Agreement for use of HP trademarks on Nuheara’s hearing aids, personal sound amplification devices and accessories.



¹ Clinical Investigation Report: Validation of Nuheara Self-Fit Hearing Aid, Version 4, 31st January 2022 by National Acoustic Laboratories, Australia

The HP Hearing PRO self-fitting OTC hearing aid brings superb medical grade hearing aid technology combined with highly desired features of wireless ear buds into a multifunctional device that will be sold in the US online and in retail stores, including Best Buy, Crutchfield, Amazon.com, and www.HPHearingPRO.com.

Initial orders have been placed from retailers and ecommerce partners for availability throughout the US. The recommended retail price for a pair of HP Hearing PRO hearing aids along with a charge case for on-the-go charging is US\$699.00.

The OTC hearing aid rule enactment in the US allows hearing aids within the OTC category, for perceived mild to moderate hearing loss, to be sold directly to consumers in retail stores or online. Access to hearing solutions in retail is something that Nuheara has been developing with its hearable products sales over the past 5 years. As such, the business is well placed to take immediate and significant advantage of the regulation changes.

This historical rule change (87 FR 50698) will forever upend the hearing aid industry in the US and unlock historical barriers to entry for the estimated 38 million Americans who experience some hearing loss and do not own a hearing aid due to the past barriers of access and affordability². Historically in the US, hearing aids are sold at an average cost of US\$4,672 per pair and can be as much as US\$10,000 or more per pair through licensed audiologist and licensed hearing aid retailers³. Now, with the ability for those with perceived mild to moderate hearing loss to purchase devices over the counter, the cost to the consumer is expected to come down substantially, averaging less than US\$1,000 per pair.

Commenting on Nuheara’s receipt of US FDA clearance and the launch of the HP Hearing PRO, Co-founder and Managing Director, Justin Miller said:

“This is a very significant day for Nuheara. Since establishing the business in 2015, we have been driven by our ambitious vision that our affordable and leading-edge hearing devices could help to solve the consumer imbalance of accessibility. There have been many major achievements and challenges along the way for Nuheara but today’s monumental milestone sees that vision become a reality, made possible by the passion, commitment and support of our great team, business partners, customers and shareholders.

“How fitting for our efforts, that concurrent with receiving our 510(k) clearance from the US FDA, over the counter sales can also commence in the US. Even better that our first hearing aid product for this new market, the HP Hearing PRO, will now be released under one of the most recognised and trusted brands in the world. Not surprisingly, the response from retailers has been strong, and we are well-placed to deliver Nuheara’s sophisticated hearing solutions to the growing OTC hearing aid market.”

US-based Nuheara CEO John R. Luna said:

“Today is historic for Nuheara and what we’ve accomplished receiving the first US FDA 510(k) clearance with the new product classification for self-fitting, air conduction, over the counter hearing aids. We are excited to bring the HP Hearing PRO to the 38 million US consumers who need an affordable over-the-counter hearing solution.

“We are proud of our global Nuheara team for the work involved to bring the product to market and drive continued value to all stakeholders. The powerful combination of Nuheara’s technology and experience along with HP’s brand recognition in the US, will translate to consumer confidence in their purchase of the HP Hearing PRO in this new OTC hearing aid category. We are already seeing signs of this from the retailers, given the high level of initial orders received.”

² On Tech: Hearing Aids for the Masses, New York Times, Apr 12, 2021

³ Technological Advancements in the Hearing Aid Industry, Ahlstrand and Green, 2021; Best Hearing Aids for 2022, Everyday Health, Aug 29, 2022

About HP Hearing PRO Self-Fitting OTC Hearing Aids

The HP Hearing PRO self-fitting OTC hearing aids are innovative products that look nothing like a traditional hearing aid. Built to medical device standards and meeting all FDA requirements for safety and efficacy, the HP Hearing PRO features the Ear ID™ self-fitting software and technology powered by Nuheara. The Ear ID™ has been clinically proven to be substantially equivalent to a professionally fit hearing aid⁴. The proprietary Ear ID™ software tests the wearer's individual hearing thresholds from low frequency to high frequency in each ear, then automatically programs the HP Hearing PRO hearing aids for each ear.

This ability for the consumer to self-fit through the HP Hearing application, for iOS and Android platform mobile devices, allow a quick and easy acclimation experience for the consumer. The entire acclimation experiences takes about 10-15 minutes from unboxing through customization of the user's personalized profile to accommodate their perceived mild to moderate hearing loss.

In addition to the HP Hearing PRO's capabilities as an OTC hearing aid, this innovative product streams media and phone calls via Bluetooth®. The Active Noise Cancellation minimises background noise for an immersive sound experience when streaming phone calls or music. Additional features include:

- HP Hearing app for iOS and Android
- Rechargeable built-in Li-ion batteries
- Charge Case for on the go charging.

Most importantly, the HP Hearing PRO has been clinically validated⁵ through research completed by the National Acoustic Laboratories to provide a 30% speech understanding improvement in the presence of noise using the directional microphone feature called Focus. This is a huge benefit for consumers in restaurants or social situations where background noise makes understanding speech difficult. Now, at the touch of the HP Hearing app, a wearer can switch the directional microphone settings to Focus on sounds towards their front, quickly allowing for immediate improvement in speech understanding.

Further information can be found at www.HPHearingPRO.com.

-ENDS-

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⁴ Clinical Investigation Report: Validation of Nuheara Self-Fit Hearing Aid, Version 4, 31st January 2022 by National Acoustic Laboratories, Australia

⁵ Ibid.

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 Securities Exchange (ASX). The Company also has a USA office located in Seattle, Washington.

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 IQbuds² 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. 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/>.