

# ASX Announcement

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## NUHEARA RECEIVES U.S. FDA REGISTRATION AND HEARING AID DEVICE LISTING

### Highlights

- Nuheara obtains US FDA establishment registration and medical device listing for a hearing aid, IQbuds<sup>2</sup> PRO;
- Alongside IQbuds<sup>2</sup> MAX, the IQbuds<sup>2</sup> PRO is the second product derived from the IQbuds<sup>2</sup> hardware platform;
- Software developments currently in train that will provide greater hearing technology sophistication and higher levels of hearing enhancement;
- IQbuds<sup>2</sup> PRO receives class 2 (medical device) 510(k) exempt classification, meaning there is no requirement to conduct clinical trials;
- Multi-product strategy to broaden sales opportunities in US by catering to a growing base of underserved customers with a wider spectrum of hearing loss;
- IQbuds<sup>2</sup> PRO expected to be launched in US later in the calendar year.

Nuheara Limited (**ASX: NUH**) (**Company or Nuheara**), transforming the way people hear by creating smart and affordable hearing solutions, is pleased to announce that the Company has received U.S. Food and Drug Administration (**FDA**) establishment registration for a medical device listing of a new hearing aid, IQbuds<sup>2</sup> PRO (**PRO**).

The PRO, alongside IQbuds<sup>2</sup> MAX (**MAX**), will be second product to be derived from the recently developed IQbuds<sup>2</sup> hardware platform. With software developments currently in train, the PRO has been designed to provide deeper levels of hearing technology sophistication, while delivering higher levels of hearing enhancement and amplification. The PRO is expected to be launched in the US later in the calendar year.

The PRO has received FDA classification as a "HEARING AID, AIR CONDUCTION WITH WIRELESS TECHNOLOGY", Device Class 2 (medical device) 510(k) exempt with an OSM product code (**Classification**). As with all hearing aids classified with the OSM product code, the FDA has classified the PRO as 510(k) exempt. This means the PRO can be sold in the U.S. without the need to conduct clinical trials or submit a 510(k) application.

Nuheara's multi-product strategy has been planned to maximise the Company's global sales opportunities by offering multiple products that support varying degrees of hearing loss. MAX will continue to meet the needs of those with mild hearing challenges. The PRO is designed to support adults with higher (moderate) levels of hearing loss and will extend Nuheara's Direct-to-Consumer strategy to the global USD \$9billion per annum (North America USD \$3.37 billion) hearing aid market<sup>1</sup>.

"This is a significant development in Nuheara's mission to make hearing health more accessible and affordable for all," said Justin Miller, CEO of Nuheara.

"Over many years the business has invested tens of millions of dollars in our proprietary hearing technology platform. The IQbuds<sup>2</sup> PRO as a hearing aid device represents further opportunities to expand Nuheara's leadership position in both hardware and software of hearing health devices. This registration effectively enables Nuheara to meet the varied hearing needs of a growing base of underserved customers with a wider spectrum of hearing loss.

"The FDA Classification we have received for PRO is separate to the FDA's proposed Over-the-Counter (OTC) hearing aid category, which was due to be issued as a new category in August 2020 but has since been delayed. It is now anticipated that the FDA will complete this at some stage during 2021. Nuheara is well placed to react once it is made.

"Utilising Nuheara's connected hearing technology platform, the Company's aspiration is to create an end-to-end hearing healthcare company by efficiently delivering hearing products, accessories and services across the Hearables, Medical Device and OTC markets."

-ENDS-

**AUTHORISED BY:**

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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. Nuheara has 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 IQbuds<sup>2</sup> MAX. Nuheara products are now sold Direct to Consumer (DTC) and in major consumer electronics retailers, professional hearing clinics, pharmacies and optical chains 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.

*Note 1: Fortune Business Insights, Hearing Aid Market Research Report, December 2020.*