

Australia's Nuheara receives historic US FDA clearance for self-fitting OTC hearing aids

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Nuheara has received the 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

Medical device and consumer electronics manufacturer at Australia, Nuheara has received 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".

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.

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.

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.