

DUEARITY WILL SUBMIT AN APPLICATION FOR APPROVAL OF A TINNITUS PRODUCT IN THE UNITED STATES

Duearity will submit an application for so-called 510(k) clearance by end of November 2022. An FDA approval will allow the company to sell Tinearity G1 in the US. The company has also started building a local sales and market organization.

Duearity has almost completed the work on the technical file to be submitted to the FDA in the US at the end of November and thus apply for 510(k) clearance. The goal is to get an approval at the end of the first half of 2023 and thus be given the permission to sell Tinearity G1 on the American market.

- We assess that the US will become Duearity's most important market in the future. Tinnitus is a major problem in the United States and receives a great deal of attention, not least because many military personnel are affected. Therefore, it is a big and important step forward when we now apply for approval for sales in the USA, says Fredrik Westman, CEO of Duearity AB.

Duearity has started work on building an organization in the US that will handle marketing, sales and distribution. The goal is for an organization to be in place during the first quarter of 2023.

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About Duearity AB (publ)

Duearity is a medtech company that develops and produces solutions aiming to relieve tinnitus symptoms and make everyday life easier for those who suffer from tinnitus. With a deep understanding of the people who have problems with tinnitus, the Company will with intelligent solutions give these people the opportunity to enjoy life. The company will offer the products Tinearity and Tinearity-AI. Tinearity transmits white noise using Bone Conduction Technology to the inner ear in order to relieve symptoms. Tinearity AI will use artificial intelligence to help people anticipate the symptoms and relieve their discomfort. The company's headquarters are located in Malmö, Sweden.

www.duearity.com.
www.tinearity.com

Attachments

Duearity will submit an application for approval of a tinnitus product in the United States