



CASE STUDY:

Levo System Personal Sound Therapy for Tinnitus

FIRST APPLE HARDWARE CLASS II DEVICE CLEARED BY THE FDA

Developed by a team at Otoharmonics® Corporation, based in Portland, Oregon, USA, with technology originally developed at Cedars-Sinai, the Levo System uses sound therapy to train the brain to ignore ringing sounds caused by tinnitus. Levo is designed to be user-friendly and capable of delivering custom sound therapy based on the specific needs of the individual.

CHALLENGES

Otoharmonics engaged StarFish Medical to help with a number of challenges: PHI (Personal Health Information) constraints, iPad and iPods as medical device components, sound output risks, patient-specific custom ear buds, software maintenance, and FDA regulatory submission assistance.

THE PROCESS

- Helped navigate PHI (Personal Health Information) constraints while collecting sufficient usage data for accurate analysis. The Levo System uses cloud based, historic anonymized data related to patient reported Tinnitus Functional Index (TFI) assessments. Post market surveillance data is combined with real world device usage.
- Managed iPad and iPods as components in a medical device (power supplies and charging scenarios). StarFish used a risk-based approach to develop a 60601-compliant device.
- Developed software and employed mitigations for sound output integrated with iOS software.
- Designed and manufactured patient-specific custom ear buds, with appropriate performance and safety measures using a risk-based approach.
- Provided software maintenance, integrated with iOS upgrades and software releases and regression testing for all new Apple software.
- Assisted successful regulatory submission to FDA.

RESULTS

The Levo System is the first Apple hardware Class II device cleared by the FDA. Otoharmonics received FDA 510(k) clearance for an iPad and iPod Touch application that treats tinnitus. The Levo System medical device provides patients a patented personal sound therapy which through neural habituation leverages the cognitive abilities of the brain to reduce the symptoms of their tinnitus and improve the quality of a patient's daily life.

BOTTOM LINE

The Levo System was awarded the top prize in the Digital Health Products and Mobile Medical Apps category of the 19th Annual Medical Design Excellence Awards competition.



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PHONE: (250) 388-3537 | TOLL FREE: 1 (877) 822-3537
info@starfishmedical.com

