keytronic

Hearing Aid

Project Timeline: 8 Months

DESIGN AND DEVELOPMENT

Complete Product Design

- Finalized customer's industrial design
- Developed mechanical 2D and 3D CAD
- Designed electrical schematics, PCB layout, and firmware
- Provided plastics tooling design support

Design Verification Testing (DVT)

- Collaborated with customer to define product specifications
- Created and executed test plans to meet all requirements
- Conducted DVT across three engineering builds
- Verified first articles for all components
- Archived all test reports in KTC database

Manufacturing Development and Support

- Developed manufacturing processes and line layout
- Completed IQ/OQ/PQ validations on all processes
- Sourced and qualified production equipment
- Designed test fixtures and developed test plans
- Created and implemented quality control plans and processes

OVERVIEW

This FDA-registered Class 2 medical device features stainless battery contacts molded into a PCBA carrier, micro-molded parts as light as 0.05g, and two ear tip styles in three sizes. It includes directional microphones, Bluetooth, app-based audio profiling, and adjustable sound modes. The double-sided rigid-flex PCBA integrates SMT components, a 51-ball micro BGA, and laser-soldered battery contacts.

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