



Cochlear Implant Manufacturer Teams with Cybernet for New Device

Advanced Bionics is a global leader in developing the most advanced cochlear implant systems in the world. They also create and deploy the hardware and software that supports these cutting-edge hearing devices, including tools to help medical professionals test, calibrate, and insert cochlear implants more efficiently.

Customer Bio



Advanced Bionics

Industry: Healthcare
Product: CyberMed Rx
HQ: Valencia, CA

Challenge

Advanced Bionics was hard at work on developing a new product called AIM, which stands for Active Insertion Monitoring. This new device would be used by surgeons and audiologists for cochlear implant surgery, post-surgical monitoring, and adjustments. As a result, it had very specific hardware requirements.

The needed a partner who could design and manufacture a tablet in an ISO 13485:2016 certified lab that could run the software and integrate with their hardware, and was also durable and came with all of the necessary IP65 and 60601-1-2 medical certifications to assist with final FDA testing. Moreover, this device would require a custom housing, new internal cables, and the creation of a new custom PCBAs. This meant Advanced Bionics would need a partner with R&D and manufacturing capabilities.

Challenge (cont.)

In addition, this customized tablet would require further testing and certification before it could go to market because it was a new medical device.

Finally, they'd need a responsive engineering team that could make adjustments to the prototype on the fly and quickly resolve the technical issues that come up during the prototyping phase.

Solution

Advanced Bionics reached out to several tablet manufacturers, searching for a tough medical tablet and a vendor with a clever design and engineering team. They came across Cybernet Manufacturing's CyberMed Rx medical tablet and were drawn to the product's design, the clean look, the drop-tested durability, and its modular capabilities. The ISO 13485:2016 medical certification ensured Cybernet's quality control met international standards, mitigating future regulatory issues that could slow the launch down.

However, in order for the AIM system to function properly, new custom PCBA boards needed to be integrated into the tablet. This alteration required a new tablet housing to be designed and manufactured to fit the circuit board, which would require further design and testing by Cybernet as well.

Advanced Bionics' and Cybernet's engineering teams worked in concert to fashion a bespoke tablet that could power the AIM device, would be true to AB's original vision, and could also help them pass 60601-1-2 certification, which was one of AB's primary concerns.

The collaboration between both engineering teams continued all through the design, manufacturing, testing, certification, and troubleshooting before release.

Results

Through a combination of hard work, mutual factory visits, and a strong channel for communication, Cybernet and Advanced Bionics successfully completed the customized CyberMed Rx tablet for the AIM system.

By forging a close relationship between groups and facilitating an interactive process, the engineering teams were able to overcome a few obstacles, meet their deadlines, and achieve the goal of earning 60601-1-2 certification.

AB praised the Cybernet engineering team for their great back-and-forth during the development cycle, tenacious problem solving skills, high-quality R&D team, and continued support. Audiologists and surgeons have praised the design, function, speed, and features of the AIM system. With Cybernet's help, AB is now able to provide a device to medical professionals that delivers real-time monitoring to cochlear implant surgeons and helps implant recipients achieve a life without limitations.

“ *It was excellent working with your engineers, they were extremely instrumental in the success of this project. I really appreciated those guys.* ”

- N.G., Project Leader, R&D
Advanced Bionics

