Esteem Clinical Trial Results

In order to gain license from the Food and Drug Administration (FDA) to commercially market and sell the Esteem, Envoy Medical went through the "premarket approval" process. The premarket approval requirements are stringent, resource intensive, and highly regulated. It is incredibly difficult to get a new medical device approved through the FDA's premarket approval process (especially a medical device that is a first-of-its-kind), but, in the end, patients can be assured that once the product's PMA application has been approved the product has met the FDA's high standards of safety and effectiveness.

One of the biggest requirements of a premarket approval application, is a closely monitored clinical trial. Envoy Medical designed the Esteem's clinical trial in close collaboration with the FDA. The overall goal of the trial was to demonstrate both the safety and the effective benefit of the Esteem to those with sensorineural hearing loss. In total, 57 patients were implanted, and then closely monitored. The data reviewed by the FDA and its panel of experts in order to grant Esteem premarket approval were data collected through 10 months on all 57 implanted patients. In addition, the patients were followed for another five years to demonstrate long-term safety and effectiveness.

Based upon the laboratory and clinical data presented in the Premarket Approval Application (PMA), there was strong evidence to support the conclusion that the Esteem is a safe and effective treatment for subjects impaired with moderate to severe sensorineural hearing loss.

Conclusions from the Final Report

- The Esteem is safe and effective in treating moderate to severe sensorineural hearing loss.
- Average benefit scores for both Speech Reception Thresholds (SRT) and Word Recognition Scores (WRS) show improved benefit over a conventional hearing aid through 5 years.
- The results show that once progression of hearing loss and programmed gain variables are accounted for, the SRT and WRS benefit is stable through 5 years..

- Serious Adverse Device Effects (SADE) through 5 year follow-up included one (1) incision breakdown after battery replacement, one (1) sore behind implant ear from glasses, and one (1) progression of outer ear infection transcanal to the implant.
- The Esteem implant procedure and therapy had no significant effect on cochlear function stability as measured by bone conduction, other than natural bilateral progression of hearing loss.
- The Esteem and the implant procedure resulted in no unanticipated adverse events.
- Subjective Esteem outcomes were better than or equal to the pre-implant hearing aid condition in Abbreviated Profile of Hearing Aid Benefit (APHAB) and the Esteem Quality of Life Questionnaire.

What do the Esteem clinical trial results mean for patients?

The device has been vetted and approved for commercial release by the FDA at the most stringent level of device classification.

There will always be risks associated with surgery, but the implant procedure was tested to ensure that all risks are minimized. Based on the results of the study, the Esteem has beneficial outcomes for those who qualify for it. When compared to a hearing aid, the Esteem has demonstrated equivalency in terms of performance using standard hearing aid test methods and metrics.

Patients enrolled in the premarket approval study were closely followed for five years. The Esteem provided uninterrupted benefit over that time and continues to demonstrate safety and effectiveness. This accomplishment speaks to the reliability and design of the innovative technology. Patient surveys demonstrate a meaningful improvement in the patient's quality of life after taking into account the many intangible benefits to the Esteem (e.g. no microphones to clean, no batteries to change daily, and an increase in social comfort). With our products, we aim to enable patients to transcend the traditional limitations of hearing aids. We are confident that our devices will continue to bring life-changing benefits to patients now and in the future.