DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

MAR 17 2010

Mr. Bernard Horwath
Regulatory Affairs
5000 Township Parkway
Envoy Medical Corporation
Saint Paul, MN 55110

Re: P090018
Esteem®, consisting of:
Sound Processor Model 2001
Sensor Model 7002
Driver Model 7502
Esteem Programmer Model 6001
Personal Programmer 8001
ISA Model 3001
Accessories
Filed: August 4, 2009
Amended: September 22, 2009, September 30, 2009, October 9, 2009, January 4, 2010, January 12, 2010, February 3, 2010.
Procode: OAF

Dear Mr. Horwath:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Esteem®. The Esteem is intended to alleviate hearing loss in patients by replicating the ossicular chain and providing additional gain. The Esteem is indicated for patients with hearing loss that meet the following criteria:

- 18 years of age or older
- Stable bilateral sensorineural hearing loss
- Moderate to severe sensorineural hearing loss defined by Pure Tone Average (PTA)
- Unaided speech discrimination test score greater than or equal to 40%
- Normally functioning Eustachian tube
- Normal middle ear anatomy
- Normal tympanic membrane
- Adequate space for Esteem implant determined via a high resolution CT scan
- Minimum 30 days of experience with appropriately fit hearing aids.

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 1 year for the Sound Processor and 2 years for the Sensor and Driver.

Continued approval of this PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

You have also agreed to conduct the following two post-approval studies:

1. *Extended Follow-up of Premarket Cohort Study*: Per agreement dated January 27, 2010 (e-mail) this study will address the following question: What is the long-term (5 years) safety and effectiveness of the Esteem device? This question will be addressed by extending the follow-up of the PMA pivotal clinical trial, which was designed as a prospective, multi-center non-randomized, 1-arm clinical trial to evaluate the safety and effectiveness of the Esteem® device. For this trial the subject acts as his or her own control. A total of 61 out of 62 patients were enrolled in the PMA pivotal clinical trial and followed out to one year. The continued access expansion study will follow these subjects out to 5-year follow-up. The study endpoints include: speech reception threshold (SRT) and word recognition score (WRS) for effectiveness; and safety endpoints include all adverse events at each follow up visit. The study protocol will include specific statistical hypotheses for the effectiveness endpoint at 5-years.

2. *The New Enrollment Study*: Per agreement dated January 27, 2010 (e-mail) this study will address the following questions: What is the long-term (5 years) safety and effectiveness of the Esteem device? Is the incidence of facial pareses/paralyses greater than 7% at 1-month? These questions will be addressed in a prospective, multi-center, non-randomized, audiologist-blinded, 1-arm observational study. For this study the subject acts as his or her own control. A total of 120 newly enrolled patients treated by newly trained surgeons at up to 10 investigational sites; consecutively treated patients will be invited to participate in this post-approval study. The study participants will be followed for 5-years. Study endpoints for effectiveness include speech reception threshold (SRT) and word recognition score (WRS). Study endpoints for safety include all adverse events at each follow up visit. A safety hypothesis will be performed at 1-month (facial paresis/paralysis). An effectiveness hypothesis will be performed at 5 years.

Within 30 days of your receipt of this letter, you must submit a PMA supplement that includes a complete protocol of your post-approval studies. Your PMA supplement should be clearly labeled as a "Post-Approval Study Protocol" and submitted in triplicate to the address below. Please reference the PMA number above to facilitate processing. If there are multiple protocols being finalized after PMA approval, please submit each protocol as a separate PMA supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm#2).

For these two post-approval studies you will submit reports on a 6-month schedule during the first two years and annually thereafter. The reports should clearly be identified as Post-Approval Study Report. Please be advised that the results from these studies should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement.

Before making any change affecting the safety or effectiveness of the device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. Final printed labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing. One of those three copies may be an electronic copy (eCopy), in an electronic format that FDA can process, review and archive (general information: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm; clinical and statistical data: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm136377.htm)

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If you have any questions concerning this approval order, please contact Daniel C. Clupper, Ph.D. at (301) 796-5620.

Sincerely yours,

MDPHO for

Donna-Bea Tillman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health