





ETYMOTIC RESEARCH, INC.
513(f) Reclassification Petition – TV-TIP Sound Amplifier

SECTION C - SUPPLEMENTAL DATA SHEET

Panel Recommendation

1. GENERIC TYPE OF DEVICE

Sound Amplifier

2. ADVISORY PANEL

Panel 77, Ear, Nose, & Throat

3. IS DEVICE AN IMPLANT (21 CFR 860.3)?

Yes No

4. INDICATIONS FOR USE IN THE DEVICE'S LABELING

The TV-TIP Sound Amplifier is a high-fidelity in-the-ear amplification device designed to amplify sound for that part of the general population considered to have normal to marginal hearing loss who desire an additional boost in sound for occasional use in various listening environments.

5. IDENTIFICATION OF ANY RISKS TO HEALTH PRESENTED BY DEVICE

General The design follows traditional principles of operation, i.e., a standard hearing aid microphone transduces the air-borne sound into an electronic signal. The signal is processed by a well known and widely used K-AMP™ circuit used in currently marketed hearing aids. The signal is converted back to air-borne sound by a standard hearing aid receiver. A standard hearing aid battery powers the device. In order to ensure safe operation for the user, the level-dependent gain and level-dependent frequency response are set so that loud sounds are not amplified. A two-position volume control allows introduction of an additional 8 dB overall gain. The maximum sound level output of the TV-TIP Sound Amplifier remains below 108 dB SPL throughout the frequency range of 200 to 8000 Hz as measured by standard testing equipment used in the hearing aid industry. Extensive research has indicated that this device is safe for the intended population. An analysis was performed per EN1441: 1997 Risk Analysis. The analysis includes the product characterization, hazard identification, risk assessment, and mitigation. All hazards identified were determined to be of low probability, minor severity, and found to pose acceptable risk considering the benefit the consumer will receive from the device.

6. RECOMMENDED ADVISORY PANEL CLASSIFICATION AND PRIORITY

Classification Class I

Priority (Class II or III Only) _____

7. IF DEVICE IS AN IMPLANT, OR IS LIFE-SUSTAINING OR LIFE-SUPPORTING AND HAS BEEN CLASSIFIED IN A CATEGORY OTHER THAN CLASS III, EXPLAIN FULLY, THE REASONS FOR THE LOWER CLASSIFICATION WITH SUPPORTING DOCUMENTATION AND DATA

8. SUMMARY OF INFORMATION, INCLUDING CLINICAL EXPERIENCE OR JUDGMENT, UPON WHICH CLASSIFICATION RECOMMENDATION IS BASED

Etymotic Research Inc. believes that the TV-TIP Sound Amplifier should not be class III by operation of section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) under the criteria in Sec. 860.3(c) due to the fact that it is much like an air-conduction hearing aid (21 CFR 874.3300). Air-conduction hearing aids have a history of being safe and effective and are classified as class I exempt. General controls are sufficient to provide reasonable assurance of the safety and effectiveness of this device. This device is intended for the general population and does not present a potential unreasonable risk of illness or injury.

9. IDENTIFICATION OF ANY NEEDED RESTRICTIONS ON THE USE OF THE DEVICE (e.g., special labeling, banning, or prescription use)

NONE. Etymotic Research Inc. does not believe that the TV-TIP Sound Amplifier device warrants a medical evaluation or a signed waiver for the medical exam by the general public, nor fitting of the device by a professional hearing aid dispenser. The device is intended to be available as an over-the-counter device (OTC), much like reading glasses. Extensive research has indicated that this device is safe for the intended population.

10. IF DEVICE IS RECOMMENDED FOR CLASS I, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM

Justification / Comments

- a. Registration / Device Listing _____
This device is much like an air-conduction hearing aid that has history of being safe and effective and is classified as class I exempt. General controls are sufficient to provide reasonable assurance of the safety and effectiveness of this device. This device is intended for the general population and does not present a potential unreasonable risk of illness or injury.
- b. Premarket Notification _____
- c. Records and Reports _____
- d. Good Manufacturing Practice _____

11. IF DEVICE IS RECOMMENDED FOR CLASS II, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM PREMARKET NOTIFICATION

- a. Exempt
- b. Not Exempt

Justifications/Comments

12. EXISTING STANDARDS APPLICABLE TO THE DEVICE, DEVICE SUBASSEMBLIES (*Components*) OR DEVICE MATERIALS (*Parts and Accessories*)

The device is factory tested prior to shipment with a standard hearing aid analyzer per American National Standards Institute, Specification of Hearing Aid Characteristics, (ANSI S3.22-1996), American National Standards Institute, New York, 1996.

13. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Health and Industry Programs (HFZ-215)
1350 Piccard Drive
Rockville, MD 20850

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Food and Drug Administration, (HFZ-215)
2094 Gaither Road
Rockville, MD 20850

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