



ETYMOTIC RESEARCH, INC.

513(f) Reclassification Petition – TV-TIP Sound Amplifier

SECTION E - EXECUTIVE SUMMARY

1. General Information:

Classification Name:	None Established
Common/Usual Name:	Sound Amplifier
Proprietary Name:	TV-TIP Sound Amplifier
Establishment Registration:	1450042
Medical Specialty:	Panel 77, Ear, Nose, & Throat
Product Code:	None Established
Regulation Number:	None Established
Device Classification:	Not Classified: Not listed in the classification regulations, 21 CFR Parts 862-892 [807.87(c)]
Contact Person:	Mead C. Killion, Ph.D., Sc.D. (hon) President 61 Martin Lane Elk Grove Village, Illinois 60007 (847) 228-0006 (847) 228-6836 Fax

2. Summary of Reasons for the Petition

Determination of substantial equivalence of the TV-TIP Sound Amplifier to a currently marketed device cannot be established, as there is currently no over-the-counter (OTC) instrument of this type available to the general public. The device described in this submission is not substantially equivalent (NSE) to any identifiable predicate device and is not classified or listed in the classification regulations, 21 CFR Parts 862-892 [807.87(c)]. Furthermore, it 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). Etymotic Research is therefore petitioning for a reclassification under section 513(f)(2) of the Act.



ETYMOTIC RESEARCH, INC.

513(f) Reclassification Petition – TV-TIP Sound Amplifier

3. Summary of Safety and Effectiveness

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 an integrated circuit and is converted back to air-borne sound by a standard hearing aid receiver. A standard hearing aid battery powers the device.

The device is manufactured and delivered completely assembled to the distributor using materials and techniques widely used by manufacturers of hearing devices and hearing protection devices.

The integrated circuit is a new circuit based on the K-AMP™ engine with the addition of a high-efficiency Class B output amplifier. This circuit is well known and widely used in currently marketed hearing aids. Signals are processed and analyzed by analog amplifiers and filters. The K-AMP technology, developed by Mead Killion in 1988, is designed as a “four-stage compression amplifier, with the greatest amount of gain for low-level inputs, less gain for the moderate-level inputs, and no gain for high-level inputs. The K-AMP amplifier also includes frequency-dependent compression, so that for low-level inputs, high frequency sounds are amplified more than low-frequency sounds.

In order to ensure safe operation for the user, the level-dependent gain and level-dependent frequency response described above 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.

4. Summary of Risks to Health

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.



ETYMOTIC RESEARCH, INC.

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5. Recommendation for Exemption

It is recommended that this device be exempt from Section 510(k) of the Act due to the fact that 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.

6. Restrictions

We do 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.

7. Existing Standards

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.