





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

**SECTION D - GENERAL DEVICE CLASSIFICATION QUESTIONNAIRE**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE --- FOOD AND DRUG ADMINISTRATION  
**GENERAL DEVICE CLASSIFICATION QUESTIONNAIRE**

FORM APPROVED: OMB NO. 0910-0138  
EXPIRATION DATE: January 31, 2006  
(See OMB Statement on Page 2)

PANEL MEMBER / PETITIONER  
Etymotic Research, Inc.

DATE  
7/10/03

GENERIC TYPE OF DEVICE  
Sound Amplifier

CLASSIFICATION RECOMMENDATION  
Class I

1. IS THE DEVICE LIFE-SUSTAINING OR LIFE-SUPPORTING ?

YES  NO

Go to Item 2.

2. IS THE DEVICE FOR A USE WHICH IS OF SUBSTANTIAL IMPORTANCE IN PREVENTING IMPAIRMENT OF HUMAN HEALTH ?

YES  NO

Go to Item 3.

3. DOES THE DEVICE PRESENT A POTENTIAL UNREASONABLE RISK OF ILLNESS OR INJURY ?

YES  NO

Go to Item 4.

4. DID YOU ANSWER "YES" TO ANY OF THE ABOVE 3 QUESTIONS ?

YES  NO

If "Yes," go to Item 6.  
If "No," go to Item 5.

5. IS THERE SUFFICIENT INFORMATION TO DETERMINE THAT GENERAL CONTROLS ARE SUFFICIENT TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?

YES  NO

If "Yes," Classify in Class I.  
If "No," go to Item 6.

6. IS THERE SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* IN ADDITION TO *GENERAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?

YES  NO

If "Yes," Classify in Class II and go to Item 7.  
If "No," Classify in Class III.

7. IF THERE IS SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS IDENTIFY BELOW THE SPECIAL CONTROL(S) NEEDED TO PROVIDE SUCH REASONABLE ASSURANCE. FOR CLASS II.

- Guidance Document
- Performance Standard(s)
- Device Tracking
- Testing Guidelines
- Other (*Specify*)

8. IF A REGULATORY PERFORMANCE STANDARD IS NEEDED TO PROVIDE REASONABLE ASSURANCE OF THE SAFETY AND EFFECTIVENESS OF A CLASS II OR III DEVICE, IDENTIFY THE PRIORITY FOR ESTABLISHING SUCH A STANDARD.

- Low Priority \_\_\_\_\_
- Medium Priority \_\_\_\_\_
- High Priority \_\_\_\_\_
- Not Applicable \_\_\_\_\_

9. FOR A DEVICE RECOMMENDED FOR RECLASSIFICATION INTO CLASS II, SHOULD HE RECOMMENDED REGULATORY PERFORMANCE STANDARD BE IN LACE BEFORE THE RECLASSIFICATION TAKES EFFECT ?

YES  NO  
 NOT Applicable

10. FOR A DEVICE RECOMMENDED FOR CLASSIFICATION / RECLASSIFICATION INTO CLASS III, IDENTIFY THE PRIORITY FOR REQUIRING PREMARKET APPROVAL APPLICATION (PMA) SUBMISSIONS.

- Low Priority \_\_\_\_\_
- Medium Priority \_\_\_\_\_
- High Priority \_\_\_\_\_
- Not Applicable \_\_\_\_\_

11. IDENTIFY THE NEEDED RESTRICTION(S)

Only upon the written or oral authorization of a practitioner licensed by law to administer or use the device

Use only by persons with specific training or experience in its use

Use only in certain facilities

Other (Specify) 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.

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

**OMB STATEMENT**

**Public reporting burden for this collection of information** is estimated to average 1-2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services  
Food and Drug Administration, (HFZ-215)  
2094 Gaither Road  
Rockville, MD 20850

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.*