



ETYMOTIC RESEARCH, INC.

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

SECTION H - DEVICE HAZARD ANALYSIS

This analysis was conducted per the following guideline:

EN1441: 1997 Risk Analysis

Device Characteristics	Hazard	Severity	Cause	Risk Estimate	Mitigation of Risk	Risk After Mitigation		
						Probability of Hazard	Severity	Acceptable Risk
<p>Intended Use:</p> <p>Enhancement of sound for normal to marginally hearing impaired.</p>	<p>1. Injury to the ear by excessively loud sounds from the device for extended period of time</p>	<p>Minor</p>	<p>Incorrect choice of receiver model</p>	<p>Low</p>	<p>Quality controlled in manufacture.</p> <p>Algorithms incorporating statistical information have been validated.</p> <p>Risk reduced by compression circuit.</p> <p>MPO limited to 108 dB SPL.</p> <p>Likelihood of further hearing loss is low based on research and experience; potential incidence is insignificant compared to further loss during aging process.</p>	<p>Low</p>	<p>Minor</p>	<p>YES</p>



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Intended Use: (continued)	2. Complications as the result of self-prescribe if the following conditions exist: Congenital deformity of the ear History of active drainage History of sudden hearing loss Significant cerumen accumulation Foreign body in ear canal Pain or discomfort Vertigo	Minor	Patient does not heed warnings in product labeling regarding contraindications.	Low	Mitigated by labeling.	Low	Minor	YES
Intended Contact: Worn in the ear canal, daily and/or occasional use	1. Cross-infection	Minor	Use of device on more than one patient	Low	Mitigated by instructions in User's Guide	Low	Minor	YES
	2. Irritation; breached skin; allergic reaction	Minor	Contact between the device tip and the ear canal.	Low	Aid can be removed if discomfort arises. Long-term experience with the use of same and common materials shows little or no problem.	Low	Minor	YES
	3. Infection due to lack of hygiene	Minor	Contact between the device tip and the ear canal	Low	Mitigated by instructions in User's Guide	Low	Minor	YES



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Materials & Components:			Contact with ear canal		1. Aid can be removed if discomfort arises. Long-term experience with the use of common materials shows little or no problem. Residuals controlled in manufacture.	Low	Minor	YES
Case	1. Bio-incompatibility: Manufacturing residuals; allergic reaction 2. Insulation degraded; leakage current	Minor		Low	2. Double insulated 1.3V battery powered device			
Ear Tip	Bio-incompatibility: Manufacturing residuals; allergic reaction	Minor	Contact with ear canal	Low	Aid can be removed if discomfort arises. Long-term experience with the use of same and common materials shows little or no problem. Residuals controlled in manufacture.	Low	Minor	YES
Microphone	Performance degraded; distortion; failure to operate	Minor	Defective component	Low	Switch off or remove if nuisance; Replace device	Low	Minor	YES
Receiver	Performance degraded; distortion; failure to operate	Minor	Defective component	Low	Switch off or remove if nuisance. Quality controlled in manufacture. Patient immediately aware device not working. Replace device.	Low	Minor	YES
Controls	Failure to operate	Minor	Defective component	Low	Quality controlled in manufacture. Patient immediately aware device not working. Replace device	Low	Minor	YES
Printed Circuit Board	Performance degraded; distortion; failure to operate	Minor	Defective component	Low	Switch off or remove if nuisance. Quality controlled in manufacture. Patient immediately aware device not working. Replace device	Low	Minor	YES



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Exchange of Energy with Patient: Acoustic energy	Change in performance – distortion Failure of device to operate	Minor	Misadjusted at factory	Low	Quality controlled in manufacture. Patient immediately aware device not working. Replace device.	Low	Minor	YES
Interaction with other devices	Not recommended for phone use.	NA	NA	NA	NA	NA	NA	NA
Environmental Influences	Temperature – Malfunction Humidity - Malfunction Atmospheric Pressure – Malfunction	Minor	Environment	Low	Switch off or remove aid. Specify maintenance and care in User Guide	Low	Minor	YES
Essential Consumables	Batteries: Incorrect selection size and type Reverse polarity	Minor	User error	Low	Instructions provided in User’s Guide. Battery door shaped for battery, type.	Low	Minor	YES
Maintenance	Improper Cleaning resulting in poor performance	Minor	User error	Low	Instructions provided in User’s Guide	Low	Minor	YES



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Delayed / Long-Term Use Effects	Change in hearing Tinnitus Skin irritation/sensitization Excess cerumen	Minor	Misadjusted at factory Improper device use Allergic reaction Individual's physiology	Low	Quality controlled in manufacture. Risk reduced by compression circuit. MPO limited to 108 dB SPL. Likelihood of further hearing loss is low based on research and experience; potential incidence is insignificant compared to further loss during aging process. Advisory in user's guide to consult physician if skin reactions occur. Remove device. Residual risk no greater than for other devices.	Low	Minor	YES