DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 23, 2016

Turtle Beach Corporation
Mr. James A. Barnes
VP Administration
12220 Scripps Summit Drive, Suite 100
San Diego, CA 92131

Re: K161331
Trade/Device Name: Hypersound Tinnitus Module
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: July 19, 2016
Received: July 21, 2016

Dear Mr. Barnes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161331

Device Name
HyperSound Tinnitus Module

Indications for Use *(Describe)*
The HyperSound Tinnitus Module is indicated for patient home use in the temporary relief of tinnitus symptoms. The device is available in HyperSound Clear 500P audio systems to generate and deliver personalized sound output to tinnitus patients with or without hearing loss and with or without hearing aids. Any fitting of the device must be done by a hearing care professional. The target population is primarily adults (18 years or older).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
for the
HyperSound Tinnitus Module
510(k) Number: K161331

Submitter:	Turtle Beach Corporation	
Contact Person:	James A. Barnes, VP Administration	
Date Prepared:	May 11, 2016	
Device Name:	HyperSound Tinnitus Module	
Device Class:	Class II	
Classification Name:	Tinnitus Masker	
Classification Regulation:	21 C.F.R. 874.3400	
Product Code:	KLW	
Predicate Devices:	K110932	GN Resound Tinnitus Sound Generator
	K111293	SoundCure™ Serenade™ Tinnitus Treatment System

INDICATION FOR USE

The HyperSound Tinnitus Module is indicated for patient home use in the temporary relief of tinnitus symptoms. The device is available in HyperSound Clear 500P audio systems to generate and deliver personalized sound output to tinnitus patients with or without hearing loss and with or without hearing aids. Any fitting of the device must be done by a hearing care professional. The target population is primarily adults (18 years or older).

DEVICE DESCRIPTION

The HyperSound Tinnitus Module is a tool to a cleared device that provides the means to create personalized sound output to provide temporary relief to patients suffering from tinnitus. It is available as a firmware option embedded in the commercially available over the counter HyperSound Clear 500P system ("500P"), a Class II, 510(k)- cleared group hearing aid (K133352). The 500P consists of an amplifier and one or two emitters (directed audio speakers) and accompanying mains power supply.

Like the 500P, the HyperSound Tinnitus Module may be used by individuals with or without hearing loss and with or without hearing aids. As part of the prescription activation of the HyperSound Tinnitus Module option, a hearing care professional ("HCP") programs a Tinnitus EQ setting for the patient which may be a standard flat EQ or a custom EQ to fit to a patient's hearing loss and/or to shape frequency output to the user's tinnitus therapy preferences.

The activation and programming by the HCP is accomplished using the HyperFit fitting software tool only available to HCPs for use with the 500P. The user may select amongst relief sounds, fine-tune up to nine EQ bans to their liking and adjust common audio settings on the 500P device such as volume and balance (left and right speaker).

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

The HyperSound Tinnitus Module is a firmware functionality option to a cleared device. It has similar features as compared to the predicate devices, as indicated in the table below.

Comparison Table

	New	***Predicate***	***Predicate***
Manufacturer	**Turtle Beach**	**GN ReSound A/S**	**SoundCure, Inc.**
Device Name	**HyperSound Tinnitus Module**	**Tinnitus Sound Generator Module**	**SoundCure Serenade Tinnitus Treatment System**
510(k)	K161331	K110932	K111293
Indications for Use	The HyperSound Tinnitus Module is indicated for patient home use in the temporary relief of tinnitus symptoms. The device is available in HyperSound Clear 500P audio systems to generate and deliver personalized sound output to tinnitus patients with or without hearing loss and with or without hearing aids. Any fitting of the device must be done by a hearing care professional. The target population is primarily adults (18 years or older).	The Tinnitus Sound Generator Module is a tool to generate sounds to be used in a Tinnitus Management Program to relieve patients suffering from tinnitus. The target population is primarily the adult population over 18 years of age. This product may also be used with children 5 years of age or older. The Tinnitus Sound Generator Module is targeted for healthcare professionals, which are treating patients suffering from tinnitus, as well as conventional hearing disorders. The fitting of the Tinnitus Sound Generator Module must be done by a hearing professional participating in a Tinnitus Management Program.	The SoundCure Serenade Tinnitus System is indicated for use in the temporary relief of tinnitus symptoms. The device is a tool to generate customized sounds to relieve patients suffering from tinnitus and can be used in a tinnitus management program. The target population is adults (18 years or older). This is a medical device and should only be used with the advice of a physician, audiologist or other hearing healthcare professional.
User Population	Adult population (18 years or older)	Adult population (>18 yrs) May also be used with children >5 yrs of age	Adult population (>18 yrs)
Where Used	Anywhere	Anywhere	Anywhere
Schedule of Use	All day	All day in all environments	All day
Mechanism of Action	Uses sound stimulus that can be frequency shaped and customized to the patient. Level of sound can be adjusted by a user volume control. Independent volume parameters per ear (inherent in the device through speaker balance control) Stimulus designed to be placed in the background and ignored	Uses noise that can be broad band to narrow band customized to the patient. Level of sound can be adjusted by a user volume control. Independent volume parameters per ear (inherent to ear specific device) Stimulus designed to be placed in the background and ignored	Uses noise that can be configured from broad band to narrow band, and pure tones customized to the patient. Level of sound can be adjusted by a user volume control. Independent volume parameters per ear Stimulus designed to be placed in the background and ignored
Technological Characteristics	Firmware functionality option embedded into a group hearing device.	Software module embedded into a digital hearing instrument.	Sounds encoded into a handheld device with earphones.
Maximum Output Characteristics	Maximum output hardware limited at 85dB SPL @ 1.5 kHz/1 meter Response: 300 Hz to 22 kHz	Maximum output fixed at 93dB SPL Output Frequency Response: Cutoffs at 500-6000 Hz	Maximum output fixed at 92dB SPL Output Frequency Response: 1 kHz to 14 kHz
Design Features	Tinnitus Sound generator of tones and nature sounds with frequency shaping Sounds customized to the patient Option to a directed audio group hearing aid 9 sound/noise tracks	Tinnitus Sound Generator of tones and nature sounds with frequency shaping Sounds customized to the patient Option to a behind the Ear hearing aid 4 sound programs / tracks	Patient Device Sound Generator with frequency shaped sounds Sounds customized to the patient Handheld device / earphones 4 sound programs / tracks (memory for up to 8)

Target Anatomy	Ear	Ear	Ear
Patient Contact Materials	None	Silicone domes in open configuration	Silicone Earphones
Transducer	Directed audio speaker	Hearing aid transducer	Earphones
Power	External power supply (100-250VAC to 48V DC)	Battery, Hearing Aid Battery	Rechargeable Lithium-ion Battery Also includes external power supply (100-250VAC to 5V DC) with power cord for recharging
Components	Firmware option embedded in 500P directed audio system (amplifier, speakers and cabling) with external mains power supply. 500P User's Guide HyperSound 500P Tinnitus Module User's Guide	Hearing Aid User Manual	SoundCure Serenade Patient Device (audio player) Earphones External power supply for recharging User's Manual
Meets Applicable Standards testing	Yes	Yes	Yes

The subject and predicate devices produce individually customizable sounds designed to provide masking relief to patients suffering from tinnitus. The subject is embedded firmware similar to GN ReSound A/S and like the Serenade device is not limited to users with hearing loss or listeners wearing a hearing aid. The addition of the tinnitus firmware module to the cleared 500P device does not affect the safety or effectiveness of the 500P device.

The subject device uses one or more directed audio speakers rather than a hearing aid or earbuds to deliver audio. There is no contact with the body or the ear and the device does not touch the patient during use. This technological difference does not present any new issues of safety or effectiveness.

PERFORMANCE DATA

Software Verification and Validation

The HyperSound Tinnitus Module is embedded firmware that has been verified and validated according to the relevant standards for medical device software and risk management procedures conducted and documented as recommended by FDA's Guidance for Industry and Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." All testing has demonstrated that the design of the HyperSound Tinnitus Module meets the established specifications necessary for consistent performance during its intended use.

The HCP HyperFit software tool is used to customize the Tinnitus Module and its application was verified and validated with commercialization of the 500P. The software for the HyperSound Tinnitus Module was considered as a "minor" level of concern, since a failure or latent flaw in the software could not directly result in serious injury or death to the patient or any operator or lead to delay in delivery of appropriate medical care that would likely lead to a minor injury. The output is limited by the 500P system and is less than the output of the predicate devices, which produce sound directly at the ear.

Clinical Study – HyperSound Tinnitus Support System

A clinical study was conducted by the California Hearing and Balance Center in La Jolla, California under a formal, written, Institutional Review Board (IRB) approved protocol. The clinical study was performed in a controlled audiology clinical office as a pre and post-

intervention clinical outcomes study using adult subjects with chronic, non- pulsatile tinnitus. This study is summarized as follows:

Objective: To assess whether high-frequency directed audio, using ultrasound technology, reduces the perception of tinnitus in subjects with chronic, non- pulsatile tinnitus.
Study Design: Pre and post-intervention clinical outcomes study.
Setting: Tertiary referral center.
Patients: Eleven adult patients with chronic, non-pulsatile tinnitus. Four subjects had unilateral chronic tinnitus and seven patients had bilateral chronic tinnitus.
Intervention(s): After being exposed to a quiet environment for 5 minutes to establish baseline tinnitus, subjects completed a validated 100 point Visual Analog Scale (VAS) for tinnitus loudness (VAS-L) and annoyance (VAS-A). Subjects, in consultation with the Investigator (a HCP), selected from a choice of customized acoustic stimuli available to play on the HyperSound 500P. The HyperSound 500P device was tuned or shaped by the Investigator to the patient's audiogram using a standard fitting algorithm. Subjects, with consultation from the Investigator, then fine-tuned (EQ) settings to customize the frequency response of the HyperSound directed audio system output and adjusted volume to their personal preference. Subjects were then exposed (listened) to the selected and customized acoustic stimulus for duration of 60 minutes. After exposure, subjects again completed the Visual Analog Scale (VAS) for tinnitus loudness (VAS-L) and annoyance (VAS-A) to indicate the degree of annoyance and loudness while in the customized acoustic stimulus.
Primary Outcome Measure: 100 point validated Visual Analog Scale (VAS) for tinnitus loudness (VAS-L) and annoyance (VAS-A).
Results: Highly significant reduction in tinnitus loudness and annoyance was observed in all subjects during exposure to a customized acoustic stimulus delivered with high frequency directed audio. The mean VAS-L scores decreased by 61% from a pre-exposure mean score of 59.6 to a post-exposure mean score of 23.5 (p=0.000053). The mean VAS-A scores decreased by 54% from a pre-exposure mean score of 64.3 to a post-exposure mean score of 29.5 (p=0.00068).
Conclusion: Delivery of a customized acoustic stimulus via high frequency directed audio using ultrasound technology demonstrated reduction in tinnitus loudness and annoyance during exposure to the stimulus.

SUMMARY OF DATA

The HyperSound Tinnitus Module has been carefully compared to legally marketed devices with respect to intended use and technological characteristics. In addition, nonclinical testing was conducted to measure output and to validate the performance of the software and ensure the module performs as intended and meets the design specifications. The clinical performance information provides data on the masking relief of the HyperSound Tinnitus Module.

The performance testing and comparison to the predicate devices demonstrate that the HyperSound Tinnitus Module is substantially equivalent to the predicate devices and the delivery of masking sound through directed audio does not present any new issues of safety or effectiveness.