K093715

PERSONA
MEDICAL

DEC 22 2010

510(k) Summary

Date: 12/17/10
510(K) Type: Traditional
Device Type: Medical

APPLICANT: Magnatone Hearing Aid Corp.
dba Persona Medical

ADDRESS: 170 N. Cypress Way
Casselberry, Fl. 32707

CONTACTS:

Don Campbell.
President Persona Medical
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Trade Name: Hearing Aid/Tinnitus Masker
Described in 21 CFR 874.3400

Product Code: ESD KLW

Device Classification: Class I (Air Conduction Hearing Aid)
Class II (Tinnitus Masker)

Proprietary Name(s):

a) Evok 900 Full Shell Hearing Device w/Tinnitus Masker Option
b) Evok 900 Half Shell/Canal Hearing Device w/ Tinnitus Masker Option
c) Evok 900 Mini Canal/CIC Hearing Device w/ Tinnitus Masker Option
d) Evok 913r Hearing Device w/ Tinnitus Masker Option
e) Evok 923 Hearing Device w/ Tinnitus Masker Option
f) Evok 928 Hearing Device w/ Tinnitus Masker Option
g) Evok 933 Hearing Device w/ Tinnitus Masker Option

Predicate Devices:

Our device is similar to the principles and tools/stimuli used by these predicate devices;

Manufacturer:	General Hearing Instruments. New Orleans, La.
Trade/Device Name:	Tranquil Combo Devices (Tinnitus Control Hearing Instrument Combination)
Regulation Number:	21 CFR 874.3400
Regulation Name:	Tinnitus Masker/Hearing Aid
Regulatory Class:	Class II/Class I
Product Code:	KLW
510(k) Number:	K974751

Manufacturer:	GN Resound 8001 Bloomington Freeway, Bloomington, MN 55420
Trade/Device Name:	TSG Module AO970-DVIR, AO970-DVIRHP, AO971-DVI
Regulation Number:	21 CFR 874.3400
Regulation Name:	Tinnitus Masker/Hearing Aid
Regulatory Class:	Class II/Class I
Product Code:	KLW
510(k) Number:	K073636

Device Description:

Our devices are a combination of a hearing aid and a tinnitus masker in the same instrument. They are prescribed for those people with hearing loss who do not have significant relief with a hearing aid alone.

Dispenser or user adjustments permit selection of broad band or high or low frequency emphasis noise and aid response. It is essentially a tinnitus masker with a hearing aid added. Programmable volume controls are provided: one for noise level and the other for hearing aid gain. The dispenser, audiologist or user can mix the amount of noise and amplification as required.

Intended Use:

The Evok 900 series are designed for individuals who experience tinnitus and also have a hearing loss. The Evok 900 series are custom and standard air conduction hearing aids with the capacity to generate broad-band noise from its circuit. The broad-band noise generator is intended for tinnitus masking therapy. It is recommended that these devices be fit by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapy.

Target Population:

The target population for this product is the adult population 18 years of age and older. The target group for this product includes individuals reporting tinnitus who can also benefit from an air conduction hearing aid.

Technological Characteristics:

The technological similarities to the predicate are based on the materials, construction and internal circuits used by Class I Hearing aids in Behind The Ear or inside the ear canal (Custom). Another characteristic is that the Hearing Aid will have the option to be a Tinnitus masking sound generator. This is achieved by programmable acoustical properties contained in the hybrid circuit built into the device.

Non-Clinical Performance Data:

The non-clinical tests submitted in this 510(k) demonstrate the electroacoustic properties of our devices and how similar in test results parameters they are.

Since these devices are basically Class I device Hearing Aids, the years these devices have been in market have established a safety track record that substantiates they are safe to market.

Substantial equivalence:

The Evok 900 series are designed to provide tinnitus masking and amplification for hearing loss in the same device. This is also true for the General Hearing Tranquil custom devices and the GN Resound Live TS BTE, OTE and RIE (also referred to in the Hearing Aid industry as RIC) products.

The Evok 900 series, General Hearing Tranquil custom devices and the GN Resound Live TS all contain circuits which can be programmed to generate sound to the ear help mask the tinnitus and decrease the perceived tinnitus.

The Evok 900 series, General Hearing Tranquil custom devices and the GN Resound Live TS Tinnitus instruments combine the amplification of a hearing aid and the masking sound of a tinnitus masker.

Risk to health:

There is no known risk associated with the use of this device because the acoustical properties of the design do not allow amplification that is considered damaging in accordance with OSHA 29 CFR 1910.95.

Conclusion:

The testing performed on the Evok 900 series are evidence that these devices are safe when used in accordance with the guidance of a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Magnatone Hearing Aid Corp. dba Persona Medical
c/o Mr. Don Campbell
President Persona Medical
170 N. Cypress Way
Casselberry, FL 32707

DEC 22 2010

Re: K093715
Trade/Device Name: Persona Medical Evok Tinnitus Masker
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus masker
Regulatory Class: Class II
Product Code: KLW
Dated: November 23, 2010
Received: November 30, 2010

Dear Mr. Campbell:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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

Enclosure

Indications for Use

DEC 2 2 2010

510(k) Number: K093715

Device Name:

1) Evok 900 Full Shell Hearing Device w/ Tinnitus Masker Option
2) Evok 900 Half Shell/Canal Hearing Device w/ Tinnitus Masker Option
3) Evok 900 Mini Canal/CIC Hearing Device w/ Tinnitus Masker Option
4) Evok 933 Behind The Ear Hearing Device w/ Tinnitus Masker Option
5) Evok 923 On the Ear Hearing Device w/ Tinnitus Masker Option
6) Evok 928 On the Ear Hearing Device w/ Tinnitus Masker Option
7) Evok 913r Receiver in Canal Hearing Device w/ Tinnitus Masker Option

Indications for Use:

The Evok series is designed for use in sound therapy for tinnitus retraining therapy, masking, or other recognized forms of tinnitus treatment. Sound therapy should be used in concert with counseling from a physician, an audiologist or other qualified tinnitus specialists.

The target population for this product is primarily the adult population 18 years of age and older. The target group for this product includes individuals reporting tinnitus who can also benefit from an air conduction hearing aid.

NOTE: The Evok 900 series Tinnitus Masker Devices are targeted primarily to the adult population over 18 years old. Our User Guide does state this but it also has a statement that reads; ***"a child with a hearing loss should be directed to an Audiologist for evaluation and rehabilitation".***
This is not meant to be a contradiction considering the user guide is generic in the general information supplied to the end user.

As part of a Tinnitus Management Program, we suggest the following recommendations applicable to clinical settings for all the devices listed above;

The Tinnitus Management treatment should include evaluation and recommendations done by a qualified audiologist, otorhinolaryngologists or

other licensed hearing healthcare professional. Since tinnitus can be associated with a number of auditory conditions, the audiologic evaluation can yield extensive information regarding the possible cause for the tinnitus and options for a successful Tinnitus Management treatment.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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Prescription Use ✓
(Per 21 CFR 801.109)