DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 27, 2015

Sanuthera, Inc.
Mr. Jeffery DiGiovanni
President
340 West State Street, Unit 45
Athens, Ohio 45701

Re: K150014
Trade/Device Name: Serenity
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: June 22, 2015
Received: June 25, 2015

Dear Mr. DiGiovanni:

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.
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4: Indication for Use Summary

510(k) Number (if known): K150014

Device Name: Serenity

Indications For Use:

The Sanuthera's Serenity device is indicated to provide a mean of sound enrichment therapy that is programmed by a hearing health care professional familiar with diagnosis and management of tinnitus as part of a personalized tinnitus management program to provide temporary relief from the tinnitus symptoms.

The target population is primarily the adult population over 18 years of age.

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5: 510k) Summary

The Summary of Safety and Effectiveness information on the Sanuthera, Inc. Serenity is being submitted in accordance with the requirements of 21 C.F.R. §807.92 and reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

I. SUBMITTER

Applicant:	Sanuthera, Inc. 340 West State Street Unit 45 Athens, Ohio 45701
Telephone:	740-591-1410
Facsimile:	928-396-9094
Contact:	Jeffery DiGiovanni
Date Prepared:	December 29, 2014

II. DEVICE

Name:	Serenity
Common Name:	Tinnitus Masking Device
Classification Name:	Tinnitus Masker, 21 CFR §874.3400
Regulatory Class:	Class II
Product Code:	KLW

III. PREDICATE DEVICE

Predicate:	Unitron Tinnitus Masker Feature, K130494, with market clearance date of May 7, 2013

IV. DEVICE DESCRIPTION

Description:	Sanuthera's Serenity is a device utilizing sound therapy as a means to mitigate the symptoms associated with tinnitus. The Serenity device works as a plug-in device to the uDirect2 bridge device, manufactured by a hearing-aid company Unitron and can be customized to a patient's tinnitus profile and then adjusted to his/her preference to play a number of sounds aimed at obscuring the ringing in the patient's ear and/or re-train patients to avoid focusing on the ringing, essentially "habituating" them away from the disease. The process of providing tinnitus therapy occur a number of ways although the most popular are Tinnitus Retraining Therapy (TRT) and Tinnitus Masking (TM). In either case, the patient is provided with the Serenity device which is custom programmed. The patient is then taken through a process of multiple protocols to set filter and volume parameters via an onboard processing unit and an onboard digital band pass filter to slowly assist in the habituation to the tinnitus.

IV. DEVICE DESCRIPTION, continue

Associated Accessories:	The following are part of the Serenity system: • The Software that is utilized by an audiologist to customize, per patient's preference during the device fitting process, the sounds aimed at obscuring the ringing in the patient's ear and/or re-train patients to avoid focusing on the ringing. • The Unitron's commercially available neck-worn uDirect2 bridge device with Unitron's Moxi Kiss Behind-the-Ear family hearing aids (K130494). • The battery charger to simultaneously charge in parallel the batteries of the Serenity and the uDirect2 bridge device.

V. INDICATION FOR USE

Indication For Use:	The Sanuthera's Serenity device is indicated to provide a mean of sound enrichment therapy that is programmed by a hearing health care professional familiar with diagnosis and management of tinnitus as part of a personalized tinnitus management program to provide temporary relief from the tinnitus symptoms. The target population is primarily the adult population over 18 years of age.

VI. COMPARISION OF TECHNOLOGICAL CHARACTERISTIC WITH PREDICATE DEVICE

Substantial Equivalency Information:	The underlying principle of sound enrichment is to provide supplementary acoustic stimulation which can help defocus attention from tinnitus and avoid negative reactions for both the subject and predicate device. The process of providing tinnitus therapy occur a number of ways although the most popular are Tinnitus Retraining Therapy (TRT) and Tinnitus Masking (TM). The patient is then taken through a process of multiple protocols to set filter and volume parameters via an onboard processing unit and an onboard digital band pass filter to slowly assist in the habituation to the tinnitus. The Serenity and predicate device are based on the following technological elements: • Sound / Noise Filtering: Allows the spectral manipulation of the sounds to a narrow band (frequency tuning) to occur at the time of fitting. • Volume Control: Can be adjusted with volume control by end user, but limited by the hearing aid. • Maximum Output Volume: Limited by hearing aid's Maximum Power Output (MPO). • Maximum Output Frequency: 10,000 Hz

Substantial Equivalency Information:	The following technological differences exist between the Serenity and predicate device: • Sound / Noise source: The Serenity and predicate device generated broad band complex sound and noise, respectively, at all frequencies across the frequency response. The frequency response is limited by hearing output (~10kHz). The usage of complex (non-noise) sounds that has been built into each sound utilized within the Serenity is consistent with scientific principles of effective sound therapy and does not raise any new issues of safety or efficacy. • Sound / Noise level and shape: The "hearing loss" may vary from ear to ear the adjustments made provide customized amplification of the audio stream received by each hearing aid (frequency- and input-dependent output levels) shall be independent and according hearing loss as established in the hearing-aid fitting activity. Serenity device is determined for both ears simultaneously the custom levels are set for each ear hearing aid even in the case of asymmetrical hearing loss. Noise level and shape determined for both ears simultaneously.

VII. PERFORMACE DATA

Biocompatibility:	The Sanuthera Serenity device works as a plug-in device to a commercially available neck-worn bridge device and transmits the audio sounds through the neck-worn device which wirelessly transmits the sounds to ear-level devices. The Serenity device or commercially available neck-worn bridge device does not have significant patient contact as the devices are typically worn over the patient clothing. Therefore, the Serenity device does not present any biocompatibility concerns. The ear-level devices specifically utilized with the Sanuthera Serenity devices are the Unitron's Moxi Kiss Behind-The-Ear (BTE) Family hearing aids. The hearing aids are intended to be worn on or in the ear on a daily basis with a typical duration of 8 – 12 hours continuously. The biocompatible properties of the materials utilized in the Unitron's Moxi Kiss BTE Family hearing aids were evaluated for the duration and type of contact as specified in ISO 10993-1:2000/AC2010 – Biological Evaluation of Medical Devices. The battery of testing include the following tests:

Test	Standard
Cytotoxicity	ISO 10993-5
Sensitization	ISO 10993-10
Irritation	ISO 10993-10

Electrical Safety and Electromagnetic Compatibility:	Electrical Safety and Electromagnetic Compatibility that were performed on the Serenity Tinnitus Masking Device. The device complies with the IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, the IEC 60601-1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and test, the FCC CFR 47 Part 15, subpart B – Unintentional Radiator and ICES-001 Issue 4:2006 for Class A Digital Apparatus .

Software Verification and Validation Testing:	The software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for the Serenity Tinnitus Masking Device was considered as a "minor" level of concern, since a failure or latent flaw in the software could not directly result in a serious injury or death to the patient or operator or lead to delay in delivery of appropriate medical care that would likely lead to a minor injury.

Animal Studies:	The Serenity Tinnitus Masking Device did not conduct any performance testing on animals.

Clinical Studies:	The Serenity Tinnitus Masking Device did not conduct any clinical testing.

Risk and Warning for Safe Use:	The Sanuthera's Serenity tinnitus masking device, being coupled to the uDirect which sends the sounds wirelessly to the hearing aids, is limited to the settings in the hearing aid's Maximum Power Output. According to OSHA regulations, the volume of the Serenity's tinnitus masker can be set to a level which could lead to permanent hearing damage when used for a prolonged period of time. Should the tinnitus masker be set to such a level in your hearing aid, your hearing healthcare professional will advise you of the maximum amount of time per day you should use the tinnitus masker. The tinnitus masker should never be used at uncomfortable levels. According to OSHA (Occupational Safety & Health Administration, U.S. Department of Labor) regulations, the maximum output of the tinnitus masker feature can be set to a level that can lead to permanent hearing loss. The maximum limit is 85 dBA SPL which corresponds to 8 hours daily use.

VII. CONCLUSION

Conclusion:	Based upon similar indications of use and technology characteristics it is concluded the Sanuthera's Serenity to be substantially equivalent to K130494, Unitron Tinnitus Masking feature.