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

September 28, 2016

Sound Options Tinnitus Treatments, Inc.
Ms. Navneet Sekhon
President
AxSource Consulting, Inc.
336 Bronte Street South, Suite 224-225
Milton, Ontario L9T 7W6 CA

Re: K161562
Trade/Device Name: Sound Options Tinnitus Treatment
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: August 24, 2016
Received: August 25, 2016

Dear Ms. Sekhon:

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 and Part 809); 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 and Part 809), 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

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)*
K161562

Device Name

Sound Options Tinnitus Treatment

Indications for Use *(Describe)*

The device, Sound Options Tinnitus Treatment, version SO 2.0, is for the temporary relief of tinnitus symptoms. The device is a software application that embeds sounds and spectral content into music to relieve patients suffering from tinnitus and can be used as part of a tinnitus management program for adults 18 years and older. The device is for prescription use by a physician, audiologist or other healthcare professional.

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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7. 510(k) Summary – Submission No K161562

7.1 Owner Information

Name: Sound Options Tinnitus Treatments Inc.
Device Trade name: Sound Options Tinnitus Treatment
Device common name: Tinnitus Masker
Address: 3841 Ridgepoint Way, Mississauga ON, L5N 7T7
Phone: 416-801-5356
Fax: N/A
Contact: Michael Chrostowski
Title: President
Email: michael@soundoptions.ca
Date of Preparation: 22 August 2016
510(k) Summary No: K161562

7.2 Regulatory Correspondent Information

Name:	AxSource Consulting Inc.
Address:	336 Bronte Street South, Suite 224-225 Milton, Ontario, L9T 7W6
Office Phone:	905-854-6059
Cell:	416-452-0100
Contact Person:	Ms. Navneet Sekhon, President
Contact Person:	Rama Joshi, Regulatory Affairs Consultant
Email:	nav.sekhon@axsource.ca
Email	rama@axsource.ca

7.3 Device Information

Trade Name	Sound Options Tinnitus Treatment
Common Name	Tinnitus masker
Classification name	Tinnitus Masker
Model Number	SO 2.0
510(k) Submitter / Holder - K161562	Sound Options Tinnitus Treatments Inc.
Device Panel	Ear, Nose & Throat
Product Code	KLW
Classification Regulation	874.3400

7.4 Indications for Use

The device, Sound Options Tinnitus Treatment, version SO 2.0, is for the temporary relief of tinnitus symptoms. The device is a software application that embeds sounds and spectral content into music to relieve patients suffering from tinnitus and can be used as part of a tinnitus management program for adults 18 years and older. The device is for prescription use by a physician, audiologist or other healthcare professional.

7.5 Predicate(s) / Substantially Equivalent Device(s)

General 510(k) information	Predicate Device(s) [510(k) summaries attached]	
Trade Name	SoundCure™ Serenade™ Tinnitus Treatment System	SoundCure Serenade Tinnitus Treatment System
Model Number	unknown	unknown
510(k) Submitter / Holder	SoundCure Inc.	SoundCure Inc.
510(k) Number	K111293	K150065
Device Panel	Ear, Nose & Throat	Ear, Nose & Throat
Product Code	KLW	KLW

7.6 Device Description

The device is a software application that embeds sounds and spectral content into music to relieve patients suffering from tinnitus and can be used as part of a tinnitus management program.
The Sound Options device software version is 2.0. The device comprises of tinnitus pitch match and audiogram submission software for health care professionals (Web Software) and Sound Options software application for sound therapy generation (manufacturer use only)

Environment of Use

Patient assessment is done at the clinic by a qualified health care professional. Software programming is done at the manufacturer's office. Sound therapy music files produced may be listened to / used by patients at home or anywhere.

Principle of Operation

Patient hearing thresholds (from a standard audiometric assessment), tinnitus type (tonal, ringing or hissing) and pitch match are supplied by qualified health care professionals to Sound Options. Traceability is achieved via unique clinic and order identifiers. Using patient audiogram and tinnitus frequency / pitch match provided by health care professionals, the Sound Options software only device, SO 2.0, modifies frequency-specific amplitudes within music tracks to provide for a customized music based sound therapy for tinnitus patients. OTS software is used to equalize the average volume of a collection of tracks (i.e. to make the average volume similar) prior to patient delivery. Customized music tracks are available to patients by download or on CD. Patients are to listen to the sound therapy at a comfortable volume level by adjusting the volume control on their personal music-playing device.

The Patient and Clinician User Manuals contain information on compatible MP3 players and headphones/earphones for use of the Sound Options sound therapy as well as how to set the volume to safe levels.

Safe levels were determined through bench testing for each of the recommended commercial device options described in the user manuals. Bench testing was conducted to ensure volume settings would not exceed 85 dBA.

7.7 Comparison of Technological Characteristics with Predicate Device(s)

Principles of operation and fundamental design and technology considerations are shared by Sound Options and its predicates.

Specifically, Sound Options and its predicate(s)
1. Are non-invasive devices and so do not deliver energy to patients
2. Do not pose any issues in terms of electrical, chemical, mechanical, thermal or radiation safety

3. Are non-sterile devices
4. Stimuli can be amplitude modulated, placed in the background and ignored. Use broadband noise. Allow user volume control. (Principle of Operation)
5. Broadband frequency sound is prescribed by qualified HCP and is custom to patient (Design)
6. Include web software (Materials)

Sound Options is validated for system compatibility and performance.

The following technological differences exist between Sound Options and its predicates. However, the difference(s) raise no safety or effectiveness concerns for the Sound Options device in comparison to its predicates. Where possible, adequate control measures have been applied.

1. Sound Options device, SO 2.0, differs from its predicates by utilizing the patient's personal music playing device while the predicate devices include a handheld device component with earphones. An OTS software used with SO 2.0 to equalize average sound volume has been validated in a clinical study as safe for sound volume management. Device labeling additionally instructs patients to adjust to a suitable sound volume using their personal music playing device.
2. Sound Options device, SO 2.0, is a software only medical device while the predicates include hardware.
3. Sound Options device, SO 2.0, is a software only medical device and involves no patient contacting material(s) while the predicates include patient contacting silicone earphones.

7.8 Performance Data

7.8.1 Performance Testing

SoundCure™ Serenade™ Tinnitus Treatment System K111293	SoundCure Serenade Tinnitus Treatment System K150065	Sound Options Software device, SO 2.0 K161562	Comparison to Predicates
System Output Performance Testing, Hardware Verification, Software Verification & Validation, Battery Useful Life In Vitro Bench Testing. Max Output fixed at 92dB SPL, Output Frequency Response: 1 – 14 kHz	System Output Performance Testing, Software Verification & Validation, Max Output fixed at 92dB SPL, Output Frequency Response: 1 – 14 kHz	Sound Options has a software only device that has been subjected to Software Verification and Validation. Output Frequency: dependent on patient headphones (commercial)	Sound Options has a software only device that utilizes the patient's personal music playing device while the predicate devices include a handheld device component with earphones. Device labeling instructs patients to adjust to a suitable sound volume using their personal music playing device. This difference raises no safety or effectiveness concerns for the Sound Options device in comparison to its predicates.

7.8.2 Standards Conformance

The Sound Options device, SO 2.0, is a software only device of minor level of concern. In accordance with IEC 62304:2006 below, the device is deemed Class A: No injury or damage to health is possible. Sound Options has justified the minor level of concern for the software device.

In addition to the software device being of minor level of concern, partial device conformance to applicable sections of various FDA recognized standards and guidance documents have been used to support device safety and performance.

Sound Options software device, SO 2.0, complies with relevant sections of the following standards and FDA guidance documents through adequate risk management and maintenance processes, software verification and validation testing to user and functional requirement specifications and adequate labeling.

- IEC 60601-1
- IEC 60601-1-11 Edition 2.0 2015-01
- IEC 62304:2006
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff, May 2005

- General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 2002
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices, September 9, 1999

The Sound Options software device and both predicate devices partially conform to the same standard IEC 60601-1.

7.8.3 Clinical Study

Objective
To determine how effective Sound Options customized music is at reducing or eliminating tinnitus symptoms over the span of several months to a year.

Location of Study
Canada

Level of Evidence

Randomized, multi-arm, "blinded" study with concurrent sham (placebo) control

Description of Subjects

Inclusion Criteria	Exclusion Criteria
Presence of mono- or bilateral tinnitus ≥12 months	History of neurological/psychiatric disorders
Agree to ≥2 hrs of daily music listening over 12 months	Medical illness that affects tinnitus therapy, severe hyperacusis, conductive or retrocochlear hearing loss, or Meniere's Disease
≥18 years old	Taking ototoxic medication during the study
English language abilities to answer questionnaires	Constant exposure to loud noise
Tinnitus Handicap Inventory (THI) score (calculated after phone interview) > 26	THI score <26
	Absolute hearing thresholds >70dB HL for frequencies <8kHz.

Primary Effectiveness Endpoint(s)

According to scientific literature cited in the clinical performance section of this 510(k), the following endpoints have high reliability and validity.

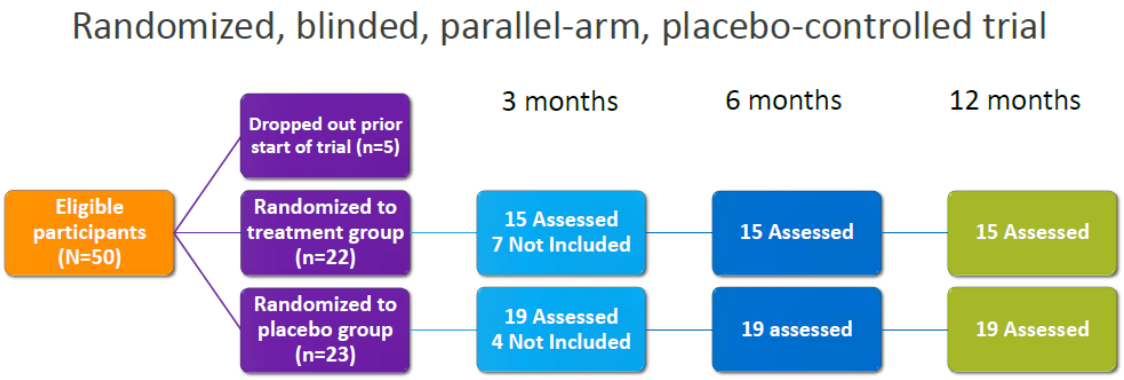
Tinnitus Handicap Inventory [**THI**] is a well-accepted measure of subjective tinnitus in tinnitus treatment studies. This 25-item self-report measure produces a global tinnitus distress score ranging from 0 to 100 points.

Tinnitus Functional Index [**TFI**] is a 25-item, self-reported clinical measure for chronic tinnitus. The total TFI score is suggested to be a good measure of the overall severity of tinnitus. In addition to overall severity, TFI also measures the negative impact of tinnitus in eight important domains: intrusiveness, reduced sense of control, cognitive interference, sleep disturbance, auditory difficulties, relaxation issues, quality of life, and emotional distress.

The **Hospital Anxiety and Depression Scale** [**HADS**] was used to assess anxiety and depression levels in participants. This 14-item self-report measure has two subscales, including depression and anxiety, and is commonly used for assessing such symptoms among somatic patients.

Study Design Overview & Subject Accountability

To examine the change in the endpoint / outcome measures from baseline to follow-ups among the treatment and placebo groups, multilevel random-intercepts linear regressions were performed for the two groups separately. Three wave variables were included as independent variables, each being an indicator of a follow-up wave. Treatment adherence was included as a control variable.



Study Results and Conclusions

In the placebo group, there were no significant changes in the endpoint / outcome measures from baseline to any of the follow-up sessions. In contrast, the treatment group reported THI and TFI total scores significantly lower at all 3 follow-up waves than at baseline. Anxiety symptoms also reduced from baseline to follow-ups, but such change was only significant at 6 months. There were no significant change in depression symptoms.

Treatment adherence level dropped significantly after 6 months of treatment. At this time point, subjects reported boredom with the music selection and repeatedly requested for new music. New music was not administered due to resource and budgetary constraints, which may have led to the participants choosing to stop listening to the music.

The results corroborate previous findings in suggesting that auditory stimuli have the potential to gradually reduce tinnitus with continued listening [Davis et al., 2008; Pantev et al., 2012, Tyler et al., 2014]. Specifically, the results indicated that significant benefits can be achieved by tailoring the auditory stimuli to the individual's hearing threshold and the tinnitus type and pitch. This is in agreement with findings reported for sound therapies using pitch match to treat tonal tinnitus [Pantev et al., 2012], as well as the observation that whether tinnitus sufferers experience an

improvement in tinnitus using hearing aids is associated with the relationship between frequency of the tinnitus sound and the output frequency range of the hearing aid [Schaette et al., 2010]. The results demonstrated a statistically significant and clinically meaningful overall effect of the personalized music therapy.

Adverse Effects

No adverse effects were reported as expected by study subjects.

Literature References

Davis PB, Wilde RA, Steed LG, Hanley PJ: Treatment of tinnitus with a customized acoustic neural stimulus: a controlled clinical study. Ear Nose Throat J 2008;87:330-339.

Pantev C, Okamoto H, Teismann H: Tinnitus: The dark side of the auditory cortex plasticity. Ann N Y Acad Sci 2012;1252:253-258.

Schaette R., König O., Hornig D., Gross M., Kempter R. (2010). Acoustic stimulation treatments against tinnitus could be most effective when tinnitus pitch is within the stimulated frequency range. Hear. Res. 269, 95–101.

Tyler R, Stocking C, Secor C, Slattery III WH: Amplitude modulated S-tones can be superior to noise for tinnitus reduction. Am J Audiol. 2014;23:303-308.

7.9 Other Information

7.9.1 Compliance to FDA Quality System Regulation (QSR) 21 CFR 820

Sound Options has been implemented with appropriate change management controls per Sound Options quality system which is compliant with FDA's Quality System Regulation 21 CFR 820. Standard Operating Procedures relevant to this 510(k) have been referenced herein.

7.9.2 Labeling Controls

Sound Options is a prescription use device and various labeling precaution statements further serve as potential device hazard mitigation controls.

7.10 Substantial Equivalence Rationale

The Sound Options software only device, SO 2.0, shares the same intended use and fundamental principles of operation, design and technology considerations with both predicate devices. The technological differences that exist do not raise any safety or effectiveness concerns for the Sound Options device in comparison to its predicates.