Starkey Laboratories, Inc.
Ka Xiong
Sr. Regulatory Affairs Specialist
6700 Washington Ave S
Eden Prairie, Minnesota 55344

Re: K201370
Trade/Device Name: Multiflex Tinnitus Technology
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: May 20, 2020
Received: May 22, 2020

Dear Ka Xiong:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Michael J. Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201370

Device Name
Multiflex Tinnitus Technology

Indications for Use *(Describe)*

The Multiflex Tinnitus Technology 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.

The Multiflex Tinnitus Technology is targeted for healthcare professionals, which are treating patients suffering from tinnitus, as well as conventional hearing disorders. The fitting of the Multiflex Tinnitus Technology must be done by a hearing professional participating in a Tinnitus Management Program.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary Per 21 CFR §807.92	
510(k) Number	K201370
Date Prepared	19 June 2020
Submitter Name & Address	Starkey Laboratories, Inc. 6700 Washington Ave. South Eden Prairie, MN 55344
Contact Person	Ka Zoua Xiong Senior Regulatory Affairs Specialist Phone: 952-915-6235 ext.6235 Email: KaZoua_Xiong@starkey.com
Alternative Contact Person	Yangjun Xing Senior Regulatory Affairs Manager Phone: 952-947-4635 ext.4635 Email: Yangjun_Xing@starkey.com
Proprietary/Trade Name	Multiflex Tinnitus Technology™
Common/Usual Name	Tinnitus Masker
Product Classification Code	KLW
Product Regulation Number and Name	21 CFR § 874.3400 – Tinnitus Masker
Device Class	II
Predicate Device	Predicate: Multiflex Tinnitus Technology™ 510(k) Number: K122876 Clearance Date: 31 Oct 2012
Device Description	Multiflex Tinnitus Technology™ (Tinnitus Multiflex) is designed to generate noise that can optionally periodically fluctuate in amplitude and frequency to provide relief for patients suffering from tinnitus. Tinnitus Multiflex is a firmware program code (algorithm) that is embedded as part of the integrated circuit (IC) in the Digital Signal Processing (DSP) stage of a hearing-aid. More specifically, Tinnitus Multiflex is an added branch of code that is separate from the normal existing hearing-aid firmware. As such, hearing-aid operating characteristics (besides tinnitus-stimulus functionalities) are not impacted by the Tinnitus Multiflex branch of code. Tinnitus Multiflex may be deployed across all Starkey hearing-aid models. Tinnitus Multiflex functionalities and parameters are enabled and adjusted by a hearing-care professional utilizing the Starkey proprietary hearing-aid programming software, Inspire. The Tinnitus Multiflex can be manually adjusted to a patient's stimulus needs or automatically adjusted via the new audiogram shaping functionality.
Indications for Use/ Intended Use	The Multiflex Tinnitus Technology 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. The Multiflex Tinnitus Technology is targeted for healthcare professionals, which are treating patients suffering from tinnitus, as well as conventional hearing disorders. The fitting of the Multiflex Tinnitus Technology must be done by a hearing professional participating in a Tinnitus Management Program.

Comparison of Subject to Predicate Device

Tinnitus Multiflex is equivalent to the predicate device (K122876) in terms of intended use, indications for use, operational characteristic, fundamental design and technological characteristic (reference **Table 1**).

Substantial equivalence of the proposed design updates in comparison to the predicate has been demonstrated through a combination of the following:

- Risk assessments
- System and software evaluations
- Design verification
- Comparative testing

Table 1: Tinnitus Multiflex compared to Predicate (K172182)

Features	**Multiflex Tinnitus Technology™ (Subject Device)**	**Multiflex Tinnitus Technology™ (Predicate Device - K122876)**
Intended Use and Indications for Use	Same	The Multiflex Tinnitus Technology 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. The Multiflex Tinnitus Technology is targeted for healthcare professionals, which are treating patients suffering from tinnitus, as well as conventional hearing disorders. The fitting of the Multiflex Tinnitus Technology must be done by a hearing professional participating in a Tinnitus Management Program.
Schedule of Use	Same	This device is intended for use for a maximum of sixteen (16) hours a day when set at the maximum output level.
Design Features	Same.	The Multiflex Tinnitus Technology™ is designed to generate broadband white noise that periodically fluctuates in amplitude and frequency to provide relief for patients suffering from tinnitus.
Mechanism of Action	The Multiflex Tinnitus Technology™ provides a flat stimulus shape (irrespective of patient thresholds) that can be manually adjusted to a patient's stimulus needs. The Multiflex Tinnitus Technology™ can also utilize the Tinnitus audiogram shaping functionality to automatically shape the tinnitus stimulus based on a patient's audiogram.	The Multiflex Tinnitus Technology™ provides a flat stimulus shape (irrespective of patient thresholds) that can be manually adjusted to a patient's stimulus needs.
Technological Characteristics	Same	Firmware based, enabled with a hearing-aid programming software (Inspire).
Circuit Type	Same	Digital

<table>
<tr><td></td><td>
<table>
<tr><td>Performance Specifications</td><td>Same</td><td>Max overall output level – 87 dB SPL
Max A-weighted overall output – 87 dB SPL
Max 1/3 octave output level – 87 dB SPL</td></tr>
<tr><td>Maximum Sound Loudness Output</td><td>Same</td><td>Maximum output in a 2cc coupler limited to 87 dB SPL.</td></tr>
<tr><td>Volume Control</td><td>Same</td><td>Tinnitus output levels are set to specified limits by the hearing-care professional. The patient volume/level controls can be enabled to provide adjustments that can decrease or increase output levels within set limits.</td></tr>
<tr><td>Power Source</td><td>Same</td><td>May use any 1.4V hearing-aid battery (size 13, 312 or 10) or be rechargeable.</td></tr>
</table>
</td></tr>
<tr><td>Summary of Non-Clinical Testing</td><td>Risk analyses and verification testing were performed for the addition of the audiogram-shaping functionality. Results demonstrated that Tinnitus Multiflex meets the device testing acceptance criteria described in the predicate submission (K122876) and is substantially equivalent to the predicate (Multiflex Tinnitus Technology™).</td></tr>
<tr><td>Summary of Clinical Testing</td><td>No new clinical testing was completed, nor relied upon, in support of this Special 510(k).</td></tr>
<tr><td>Statement of Equivalence</td><td>Changes to the subject device, Tinnitus Multiflex, do not raise new questions of safety or effectiveness. The addition of the audiogram-shaping functionality was assessed by appropriate risk management methodology and addressed with verification and validation testing.

Acoustic measurements of output levels, utilizing previously defined limits, were used during verification to ensure that the maximum allowable stimulus level for the subject device was the same as the predicate device. All results passed, and the results of the verification and validation testing support that the addition of the audiogram-shaping functionality does not impact safety and effectiveness.

The subject and predicate devices are technologically identical and neither the subject device safety and effectiveness, nor intended use is impacted. The results support substantial equivalence of the subject device to the predicate device (K122876).</td></tr>
</table>