



Food and Drug Administration  
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Silver Spring, MD 20993-0002

October 8, 2015

KW Ear Lab, Inc.  
Mr. Sungwoo Cho  
Vice President/General Counsel  
18655 South Bishop Ave  
Carson, CA 90746

Re: K151719  
Trade/Device Name: Reve134  
Regulation Number: 21 CFR 874.3400  
Regulation Name: Tinnitus Masker  
Regulatory Class: Class II  
Product Code: KLW  
Dated: June 25, 2015  
Received: July 1, 2015

Dear Mr. Cho:

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



**Exhibit 6 510(k) Summary**

**510(k) Summary  
(REVE134)**

**Submitter:** KW EAR LAB, INC.  
18655 South Bishop Ave, Carson, CA 90746  
Phone: (310)-747-1390

**Contact Person:** Sungwoo Cho  
KW EAR LAB, INC.  
18655 South Bishop Ave, Carson, CA 90746  
Phone: (310)-747-1390

**Date Prepared:** May 30, 2015

**Device Name:** REVE134

**Device Class:** Class II

**Classification Name:** Tinnitus Masker

**Classification Regulation:** 21 C.F.R. 874.3400

**Product Code** KLW

**Predicate Devices:** K133308 Tinnitus SoundSupport, Oticon  
K110932 Tinnitus Sound Generator, GN Resound

**Intended Use / Indication for Use:**

REVE134 is a sound generating software used in a Tinnitus Management Program designed to provide temporary relief for people experiencing tinnitus symptoms. It is intended primarily for adults over 18 years of age, but may also be used for children 5 years of age or older. REVE134 is for use by hearing healthcare professionals who are familiar with the evaluation and treatment of tinnitus and hearing losses. A hearing healthcare professional should recommend that a patient listen to the REVE134 signal for 30 minutes twice a day at the barely audible level (minimally detectable level).

**Technological Characteristics:**

KW EAR LAB's REVE134 consists of software installed in PC (desktop or laptop computer). REVE134 is fitted to the patient by the hearing healthcare professional. The software enables qualified professional to create customized sounds with specific frequency range for sound therapy/masking. REVE134 software can generate either modulated white noise (233~12912 Hz) or modulated narrow

band noises or tones with specific frequency range. One narrow band noise has a frequency range of approximately 1/3 octave.

**Performance Data:**

KW EAR LAB’s REVE134 software installed and embedded in PC has been verified and validated according to relevant standards for medical device software and risk management procedure (Fig. 1). In all verification and validation process, KW Ear lab’s REVE134 functioned properly as intended and the performance observed was as expected.

Fig. 1

Standard No.	Standard Title
IEC 62304	Medical device software – Software life-cycle processes
ISO14971:2007	Medical devices- Application of risk management to medical devices

**Substantial Equivalence:**

KW EAR LAB REVE134 is as safe and effective as Oticon’s Tinnitus SoundSupport (K133308) and GN Resound’s Tinnitus Sound Generator (K110932). As shown in the table below, KW Ear lab’s REVE134, Oticon’s Tinnitus SoundSupport (K133308), and GN Resound’s Tinnitus Sound Generator (K110932) have the same intended use and similar indications, technological characteristics, and principles of operation. Minor technological differences do not present any new issues of safety or effectiveness. Thus, KW Ear lab’s REVE134 is substantially equivalent to Oticon’s Tinnitus SoundSupport (K133308), and GN Resound’s Tinnitus Sound Generator (K110932).

**Comparison Table:**

**KW Ear lab Inc. REVE134**

**Substantial Equivalent Chart**

Device	New	Predicate	Predicate
Manufacturer	KW Ear lab	Oticon	GN Resound
Name	REVE134	Tinnitus SoundSupport	Tinnitus Sound Generator
510(K) No.		K133308	K110932
Indication for Use	REVE134 is a tool to generate sounds to be used in a Tinnitus Management Program to relieve patients suffering from tinnitus.	Tinnitus SoundSupport is a tool intended to generate sounds to provide temporary relief to patients suffering from tinnitus as part of a	The Tinnitus Sound Generator is a tool to generate sounds to be used in a Tinnitus Management Program to relieve patients

	<p>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.</p> <p>REVE134 is targeted for hearing healthcare professionals who are familiar with the evaluation and treatment of tinnitus and hearing losses. A hearing healthcare professional should recommend for a patient to listen to the REVE134 signal for 30 minutes twice a day at the barely audible level (minimally detectable level). A default starting level of REVE134 is 54 dBr. A hearing healthcare professional needs to adjust this default value of '54 dBr' into patient's barely audible level.</p>	<p>tinnitus management program.</p> <p>The target population is the adult population (&gt;18yrs). Tinnitus SoundSupport is targeted for licensed hearing care professionals (audiologists, hearing aid specialists, or otolaryngologists) who are familiar with the evaluation and treatment of tinnitus and hearing losses.</p> <p>The fitting of Tinnitus SoundSupport must be done by a hearing care professional participating in a tinnitus management program.</p>	<p>suffering from tinnitus.</p> <p>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.</p> <p>The Tinnitus Sound Generator Module is targeted for healthcare professionals, which are treating patients suffering from tinnitus, as well as conventional disorders.</p>
<b>User Population</b>	Primarily adult population (>18yrs), can be used for patients >5yrs	Adult population (>18yrs)	Primarily adult population (>18yrs), can be used for patients >5yrs
<b>Schedule of Use</b>	All day	All day	All day in all environments
<b>Mechanism</b>	<p>Volume is set by HCP and can be adjusted by patients, when in use. Default level fixed.</p> <p>Amplitude modulation noise and frequency modulation pure tone</p>	<p>Volume is set by HCP and can be adjusted by patients, when in use. Default level fixed.</p> <p>Amplitude modulation and steady noise.</p>	<p>Volume is set by HCP and can be adjusted by patients, when in use. Default level fixed.</p> <p>Amplitude modulation and steady noise.</p>
<b>Technological Characteristics</b>	Software module embedded into a digital hearing instrument platform. Sound files generated by the REVE134 can be used only in a digital hearing instrument platform which provides MP3 codec (e.g.,	Software module embedded into a digital hearing instrument platform	Software module embedded into a digital hearing instrument platform

	MP3 players).		
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