K040330

APR 1 2 2004

510(k) Summary for Quiescence Software

Date summary was prepared	November 13, 2003
Applicant's Name & Address	Spectral Visualization and Development (SVD) Inc. 921 College Hill Road, Fredericton, NB E3B 6Z9 Canada
Establishment Number:	3004176728
Contact Person, Telephone and email address:	Dennis Woo 506-460-1625 dwoo@svdinc.com
Device Trade or Proprietary name:	Quiescence
Classification name:	Tinnitus masker
Classification of Device	Class II
Product Code:	KLW
Marketed device to which the claim of substantial equivalence is made:	K030791 TinniTech ANMP System

Comparison to equivalent device Quiescence vs. TinniTech ANMP System (K030791):

	Quiescence Software K040330	TinniTech ANMP System K030791
Intended Use	Creating masking sound to mask tinnitus as part of tinnitus management program.	Continuously and intermittently mask tinnitus as part of a tinnitus management program with masking noise.
Target Population	The software is targeted for healthcare professionals to create custom masking sounds for tinnitus patients. The masking sound created by the healthcare professional may be used by adult (age 18 years and over) that are participating in a tinnitus management program.	Adults (18 years and over) with and without high frequency loss, with tinnitus who are participating in a tinnitus management program.

	Quiescence Software K040330	TinniTech ANMP System K030791
Operation		
Audio Signal Technology	Digital	Digital
Available noises/sounds	Pure tone, FM tone, pulse pure tone, narrowband noise, speech noise and white noise. Except for speech noise, and white noise, the center frequency of other sounds is adjustable from 100 Hz to 20000 Hz.	Pre-adapted to the patient's hearing characteristics, a wide selection of musical sounds incorporating Tinnitus Masking noise (20Hz – 20 kHz) digitally recorded on mini compact disc in MP3 format.
Medium	Healthcare professional will use the software to generate the desire masking sound(s). The resulting sound(s) can be saved in any medium that is convenient to the patient. A common medium would be an audio digital compact disc (CD).	Two mini CDs and can be expanded by providing a variety of music on additional discs.
Volume Control	Volume is controlled by the patient. Healthcare professionals are provided with warning messages to be included with the masking sounds.	User controlled with warning in the User Instruction Manual.
Distribution	The Quiescence software is only available to otolaryngologists, audiologists and hearing-aid dispensers. The masking sound(s) created by the healthcare professional is directed to the tinnitus patient under the direct supervision of the healthcare professional.	To be sold via direct and indirect channels involving an appropriately qualified healthcare professional.

	Quiescence Software K040330	TinniTech ANMP System K030791
Energy delivered	The output of most computer sound card can provide an output exceeding 85 dBA which requires the proper observation of the OSHA permissible noise exposure standard. The user's guide of Quiescence includes the list of permissible noise exposure duration and the corresponding noise level. The software will also display a warning message to alert healthcare professional when the output is going to exceed a user-defined limit. The default limit of the software ensures that the output is below 85 dBA.	Max. output could exceed 85 dBA
Characteristic	New device	Predicate device
Where used	The healthcare professional will use Quiescence to generate suitable masking sound(s) for the tinnitus patient to use at home under direction supervision of the healthcare professional.	Home used under the management of an appropriately qualified healthcare professional.
Instructions	The Quiescence device comes with a User's Manual.	The TinniTech ANMP System comes with a User's Guide.

Description of Device

Quiescence provides a means for healthcare professionals to custom-make masking sounds for tinnitus patients. This software allows the healthcare professional to try different masking sounds on the patients until one or

	more suitable ones are found. The masking sounds will be stored to the computer hard disk. This allows the stored masking sound to be written or recorded into other convenient formats such as CD and MP3 player for playback.
Intended Use of Device	Creating masking sounds to mask tinnitus as part of a tinnitus management program.
Brief discussion and conclusion of non-clinical tests and their results.	The key to a tinnitus masker is the accuracy of the masking sound. There is no better way to qualify the accuracy of the masking sound using engineering tests. The masking sound produced by the Quiescence software was tested repeatedly to ensure that the sound matched the intended output. The algorithms that generate the masking sound were analysed and the generated sound was also analysed before and after it passed through the sound output device (headset). When analyzing the masking sound, spectrum analysis was used to ensure the proper frequency content in the masking sound. The results indicated that all the masking sounds generated matched the intended masking sound output. This clearly indicates the masking sound generated by the Quiescence software will be as effective as what other masking devices would generate.

Information required under Title 21, Section 874.3400 and not already provided above

Risk	There is no risk associated to the masking sounds\ that Quiescence created if they are used as directed by the healthcare professional.
Hearing Healthcare Professional diagnosis	The masking sound is only available though qualified healthcare professionals such as audiologist or otolaryngologist.
Benefits	Like other tinnitus maskers, the masking sound generated by the Quiescence software may provide relief to tinnitus symptoms when utilized properly under the directions of the healthcare professional.
Warnings	The Quiescence software is capable of delivering sound output level of over 85 dBA which exceed the OSHA standard. To avoid hearing damage, Quiescence will alert the healthcare professional when the output level is set beyond 80 dBSPL. This output level is chosen to ensure that the

corresponding dBA-weight output level will not be exceeded throughout the frequency range of Quiescence. The following warning label is proposed to be included with the recording of the masking sounds generated by Quiescence:

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF AN OTOLARYNGOLOGIST, AUDIOLOGIST OR HEARING-AID DISPENSER. FURTHEREMORE, THIS DEVICE MAY HARM YOUR HEARING IF IT IS NOT USED AS DIRECTED BY YOUR OTOLARYNGOLOGIST, AUDIOLOGIST OR HEARING-AID DISPENSER.

Furthermore, the healthcare professional should provide the patient with adequate instruction to use the masking sound(s) at home. Appendix A of the Quiescence User's Guide contains cautionary and usage information for tinnitus patients that healthcare professionals should distribute before handing out the hard copy of the masking sounds to patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 2 2004

Spectral Visualization Ndd Development (SVD) Inc.
c/o Dennis Woo, Ph.D., P.Eng.
921 College Hill Road
Fredericton, NB E3B 6Z9
Canada

Re: K040330
Trade/Device Name: Quiescence™
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: February 9, 2004
Received: February 25, 2004

Dear Dr. Woo:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040330

Indications for Use

510(k) Number (if known): K040330

Device Name: Quiescence

This software device, Quiescence™, is indicated for use by otolaryngologists, audiologists, and hearing-aid dispensers (collectively referred to as healthcare professionals) for generating custom masking sounds to mask tinnitus as part of a tinnitus management program. The target population of the device is adults (18 years and over) who report experiencing tinnitus, which may or may not be accompanied with hearing loss. Patients should receive a medical evaluation by a licensed physician who specializes in diseases of the ear to rule-out medically or surgically treatable diseases for which tinnitus is a symptom before proceeding with non-medical tinnitus management.

Prescription Use: X AND/OR Over-The-Counter Use: _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Division Sign-Off) (please do not write below this line – continue on another page if needed)

Division of Ophthalmic Ear, Nose and Throat Devices

Concurrence of CDRH, Office of Device Evaluation ODE

510(k) Number Janus K Kraus Ph.D