K033108

OCT 27 2003

510(k) SUMMARY

TRADE NAME OF DEVICE(S):	Vivo 200 DPS VivoScan™ Version 2.0 OAE Audiometer.
COMMON NAME:	Otoacoustic Emissions Test Instrument.
CLASSIFICATION:	The Vivo 200 DPS VivoScan™ Version 2.0 is Class II Medical Device (21CFR874.1050, Procode: EWO).
COMPANY NAME and ADDRESS:	Vivosonic Inc. 56 Aberfoyle Crescent, Suite 620 Toronto, ON Canada M8X 2W4
CONTACT PERSON:	Yuri Sokolov, PhD, President & CEO
TELEPHONE NUMBER:	(877)-255-7685
FAX:	(416)-231-2289

DESCRIPTION OF DEVICE:

Vivo 200 DPS™ Version 2.0 is a diagnostic system that assists clinical professionals in the assessment and screening of cochlear function. The device includes a probe with a disposable tip that fits in the patient's ear canal. The probe contains a tiny speaker for stimulating the patient's ear with sound and a microphone for receiving low-volume otoacoustic emissions (OAEs).

The probe is connected to a probe adaptor circuit that generates the acoustic stimuli and amplifies the OAE responses. The probe adaptor circuit initiates stimulus delivery under the control of a dedicated notebook computer. The notebook computer reads the response from the probe adaptor and processes the signal digitally to measure and detect the OAE signal level, estimate the noise and display the results.

The Vivo 200 DPS™ Version 2.0 probe adaptor is capable of producing stimuli and eliciting Transient Evoked OAEs (TEOAEs) and Distortion Product OAEs (DPOAEs). TEOAEs are produced by the cochlea in response to short duration click sounds. DPOAEs are produced in response to two continuous pure tones that are close to each other in frequency.

The Vivo 200 DPS™ Version 2.0 software contains digital signal processing algorithms for measuring and detecting responses to both types of OAEs. The DPOAE and TEOAE responses are acquired and detected using the same probe, probe adaptor circuit and computer interface. The stimuli for both types of OAEs use the same probe, amplification circuitry and computer interface but utilize different modules in the probe adaptor circuit to generate their respective waveforms.

Software running on the notebook computer under the Windows XP™ operating

system incorporates a graphical user interface that allows the user to configure the OAE test protocol, initiate and stop the test, print, save and review test results, and store patient information.

INDICATION FOR USE:

The Vivo 200 DPS VivoScan™ Version 2.0 is indicated for use when it is necessary for a trained health care professional (for example an Audiologist) to measure or determine cochlear function by measuring, recording and displaying otoacoustic emissions. This device does not measure hearing, but helps to determine whether or not a hearing loss may be present, requiring further evaluation.

The Vivo 200 DPS VivoScan™ Version 2.0 does not measure hearing per se, but measures whether or not the cochlear hair cells are functioning. This device does not determine hearing levels, but allows the operator to establish specific pass or refer criteria.

The Vivo 200 DPS VivoScan™ Version 2.0 is indicated for patients of all ages from newborn through adults, to and including geriatric patients. The otoacoustic emissions test is especially indicated for use in testing individuals for whom behavioral audiometric results are deemed unreliable, such as infants, young children, and cognitively impaired or uncooperative adults.

The Vivo 200 DPS VivoScan™ Version 2.0 is a prescription device. The labeling instructions and user operations are designed for trained professionals.

ELECTRICAL SAFETY: The Vivo DPS VivoScan Version 2.0 is designed to meet the EN 60601 series of standards for electromagnetic (EMI) and electrical safety required for Medical Electrical Equipment.

Substantial Equivalence Comparison

The Vivo 200 DPS™ Version 2.0 device is substantially equivalent to our currently marketed Vivo 200 DPS™ OAE Audiometer.

Comparison Parameter	**Difference**
Intended use	Essentially the same.
Patient population	No difference
Patient connection and connection sites	No difference
Hardware configuration	No difference

Software algorithm	The propriety code in the VIVO 200DPS Version 2.0 uses averaging and Fast Fourier Transform (FFT) to process Transient Evoked Otoacoustic Emissions (TEOAE)[1].
User Manual	The User Manual has been updated and revised to provide information and use instructions for the TEOAE measurement capability.
Safety Characteristics	There is no difference in patient connection and isolation.

[1] Transient Evoked Otoacoustic Emissions (TEOAE) functionality was added to the Vivo 200 DPS™ Version 2.0. TEOAEs are OAEs produced in response to a short duration sound. These short-duration stimuli may be tone bursts or clicks.

Date Summary Prepared: October 7, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2003

Vivosonic Inc.
Yuri Sokolov, Ph.D.
President & CEO
56 Aberfoyle Crescent, Suite 620
Toronto, ON Canada M8X 2W4

Re: K033108
Trade/Device Name: Vivo 200 DPS VivoScan™ Version 2.0 OAE Audiometer
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO
Dated: September 29, 2003
Received: September 30, 2003

Dear Dr. Sokolov:

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) 594-4613. 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,

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

K033108/A1

510(k) Number (if known): K033108

Device Name: **Vivo 200 DPS VivoScan™ Version 2.0**

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

✓
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K033108

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