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

MAY 11 2017

Mr. Emanuel A. Rosen, M.S., R.Ph.
EARE Consulting Service
P.O. Box 13009
88112 Eilat
ISRAEL

Re: K970180
Trade/Device Name: VSA 3000 Vibratory Sensory Analyzer
Regulation Number: 21 CFR 882.1200
Regulation Name: Two-point discriminator
Regulatory Class: Class I
Product Code: LLN
Dated: January 8, 1997
Received: January 17, 1997

Dear Mr. Rosen:

This letter corrects our substantially equivalent letter of April 25, 1997.

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 Parts 801 and 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 Parts 801 and 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" (21CFR 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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K970180

Device Name: VSA-3000 Vibratory Sensory Analyzer

Indications For Use: For use in the measurement of vibratory thresholds, or sensibility, in clinical situations where various neuropathies may exist.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970180

Prescription Use X OR **Over-The-Counter Use**
(Per 21 CFR 801.109)

K970180

APR 25 1997

510(K) SUMMARY
[as per 21 CFR 807.92]

8 January, 1997

Product: **VSA 3000 - Vibratory Sensory Analyzer**

Submitted by:

Emanuel A. Rosen - official correspondent for
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Other commercially available devices:

Bio-thesiometer - Bio-Medical Instruments Co. - available for over 50 years.

Vibraton II, Vibration Sensitivity Tester - **Sensortek - K863607** approved 1986

Case IV - WR Medical Electronics Co. - K910624 approved in 1993

The **VSA 3000 - Vibratory Sensory Analyzer** is a computerized device for the quantitative assessment of large nerve fiber dysfunction, designed for both clinical and advanced research applications. It measures the sensory threshold for vibration. These thresholds deviate from the normal range in:

Metabolic neuropathies
Neurological disease associated with the workplace
Neuropathies due to drug toxicity
Pain assessment
Lesions of the central nervous system

Vibratory testing is also a useful tool in tracking the progression of disease or response to treatment.

The **VSA 3000** can also be used in the early detection and clinical evaluation of peripheral nerve dysfunction as well as being a useful tool in tracking the progression of disease or response to treatment.

The various devices used in Vibration Threshold Measurement all operate by means of applying varying amounts of vibration to the skin by the use a controller which allows the operator to vary the amount of vibration delivered.

The patient then indicates awareness of the vibrations either verbally or, in the **VSA 3000**, by pressing a patient response button. There are various protocols available for testing sensitivity such as Forced choice, Limits, Levels and Staircase, from which the tester may choose.

The **VSA 3000** and **Case IV** both have data processing features while the **Bio-Thesiometer** and the **Vibraton II** do not.

All the devices are similar in their energy source and design as well as meeting the various standards for clinical safety.

The **VSA 3000** is designed and manufactured to meet various domestic and international standards such as:

UL 544; UL 2601-1/1994; EN 60601-1-2.