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. James R. Greenwood, Ph.D., M.P.H
Chairman, Regulatory Advisor
Osachi Co., Ltd.
c/o International Medical Device Partners, Inc.
3027 E. Sunset Rd., Suite 105
Las Vegas, NV 89120

Re: K072882
Trade/Device Name: PS-2100
Regulation Number: 21 CFR 882.1200
Regulation Name: Two-point discriminator
Regulatory Class: Class I
Product Code: LLN
Dated: October 10, 2008
Received: November 7, 2008

Dear Dr. Greenwood:

This letter corrects our substantially equivalent letter of January 8, 2009.

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 FDA

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

K072882

JAN – 8 2009

C. 510(K) summary

1. General Information

Submitter's Name	: OSACHI Co., Ltd.
Address	: 9-11, Osachikohagi 2-chome, Okaya-shi, Nagano, Japan
Telephone	: 81-266-280866
Contact Person	: Dr. James R. Greenwood Ph. D., M.P.H.
Registration Number	: 8043882

2. Device

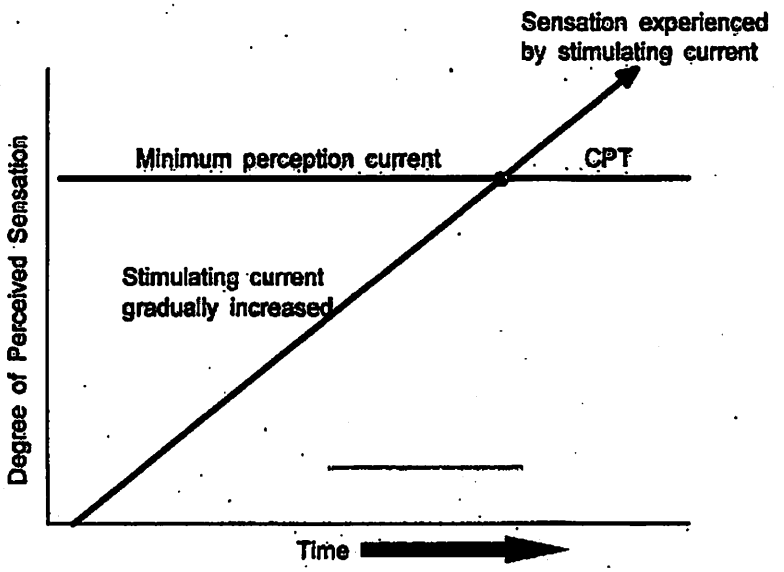
Name	: PS-2100
Trade Name	: PS-2100
Common Name	: Sensory Nerve Threshold Measurement System
Classification Name	: device, vibration threshold measurement
Product Code	: LLN
Class	: II

3. Identification of Legally Marketed Devices

Name	: NEUROMETER
K Number	: K853608

4. Product Overview

The PS-2100 is a type of Sensory Nerve Threshold Measurement System Device. The electrical stimulus is applied in gradually increasing amounts to the electrode attached to the patient. Disposable gel electrodes are attached to the patient connecting the electrode. The current value at which the patient initially senses the stimulation is referred to as the Current Perception Threshold (C.P.T.) value. Measurement may be conducted in one of two modes – Standalone mode by which the device itself is used for measurements, and System mode whereby the device is connected to a personal computer for administration of data. The patient is provided a hand switch to cease measurement at any time during the test.
For detailed information refer to Device Description.



5. Indication for use

PS-2100 is a device for the quantitative detection of sensory neurological impairments. The population of subjects for whom this device may be used include any individual capable of communicating their perception of cutaneous sensation. PS-2100's examination may be conducted as part of a routine neurological examination or as a screening procedure. This device may be used by healthcare professionals to evaluate or diagnose a patient for peripheral neuropathy.

6. Standard compliance list

Application Standard	ISO13485:2003 IEC60601-1:1988+A1+A2 IEC60601-2-40:1998	IEC60601-1-1:2000 IEC60601-1-2:2004 ISO10993-1:2003

Applicant: OSACHI CO., LTD.

510(k) Number : K072882

Device Name: PS-2100

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Prescription Use ✓ AND/OR Over-the-Counter-Use _____

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K072882