

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

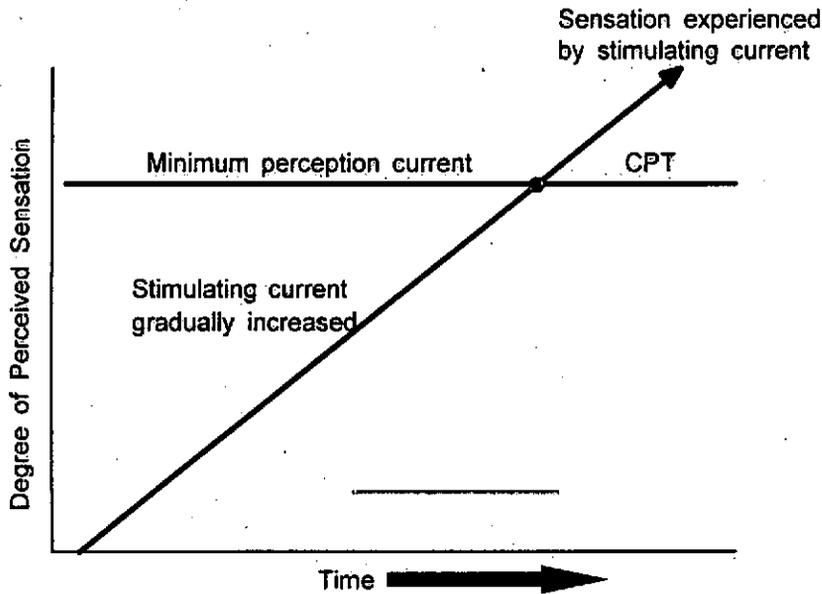
Name : PS-2100
Trade Name : PS-2100
Common Name : Sensory Nerve Threshold Measurement System
Classification Name : device, vibration threshold measurement
Product Code : LLN
Class : II

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 2008

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

Re: K072882
Trade/Device Name: PS-2100
Regulatory Class: Unclassified
Product Code: LLN
Dated: October 10, 2008
Received: November 7, 2008

Dear Dr. Greenwood:

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.

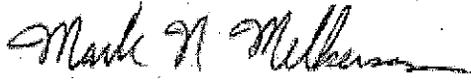
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – James R. Greenwood, Ph.D., M.P.H.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Applicant: OSACHI CO., LTD.

510(k) Number : K072882

Device Name: PS-2100

Indications for Use:

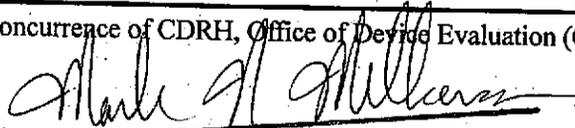
PS-2100 is a device for the quantitative detection of sensory neurological impairments. The population of subjects for whom this device may be used include any individual capable of communicating their perception of cutaneous sensation. PS-2100's examination may be conducted as part of a routine neurological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

Prescription Use AND/OR
(Part 21 CFR 801 Subpart D)

Over-the-Counter-Use
(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

Page 1 of 1