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5. 510(K) SUMMARY

K121184

510(k) Summary
for
NeuroMetrix SENSUS™

SPONSOR

NeuroMetrix, Inc.
62 Fourth Avenue
Waltham, MA 02451 USA

Contact Person: Rainer Maas
Telephone: (781) 314-2781
Date Prepared: July 23, 2012

DEVICE NAME

Proprietary Name: SENSUS
Common/Usual Name: Transcutaneous Electrical Nerve Stimulator, TENS
Classification Name: 882.5890 GZJ
Transcutaneous electrical nerve stimulator for pain relief

PREDICATE DEVICE

EMPI Active Transcutaneous Nerve Stimulator (K090922)

INTENDED USE

The NeuroMetrix SENSUS device is intended for use as a transcutaneous electrical nerve stimulator for the symptomatic relief and management of chronic intractable pain.

DEVICE DESCRIPTION

SENSUS is a one-channel transcutaneous electrical nerve stimulator with a single output mode. The stimulator utilizes a microprocessor running embedded software to control a high-voltage circuit that generates stimulating pulses with specific technical characteristics including waveform shape, current intensity, waveform duration and frequency. The stimulator is powered by a permanent rechargeable Lithium-Ion battery that is recharged through a USB cable connected to an AC adapter.

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The stimulator delivers electrical stimulation to the patient through two disposable, single-patient use electrodes placed on the patient's body. The stimulator, as labeled, is for use with legally available electrodes. The electrodes should be self-adhering with an electrical connection made through a male medical snap connector and an electrode area ≥ 20 cm^2. The stimulator connects to the electrodes through a patient cable consisting of two lead-wires that terminate in an insulated female medical snap connector.

The stimulator has a push-button that initiates and halts stimulation. Taps to the stimulator enclosure, detected by an embedded accelerometer, control the stimulation intensity. The push button serves the dual purpose of powering up the device from a standby state and initiating and halting stimulation.

COMPARISON TO PREDICATE

The NeuroMetrix SENSUS device and predicate Empi Active Transcutaneous Nerve Stimulator (ACTIVE) have the same intended use, i.e., they are intended for the symptomatic relief and management of chronic intractable pain. The SENSUS Indications for Use represent a subset of the predicate Indications for Use. Specifically, while both SENSUS and the predicate are indicated for the relief and management of chronic intractable pain, the predicate is additionally indicated for the relief of pain associated with arthritis and as an adjunctive treatment for post-surgical and post-trauma acute pain. Both are prescription devices to be used under the direction of a medical professional.

SENSUS and the predicate have the same basic technological characteristics as listed below.

- One stimulation channel
- Single output mode
- Patient controlled intensity
- LED indicators (no intensity display)
- Powered by rechargeable battery

SENSUS and the predicate device have output characteristics that are within the range of output parameters of legally-marketed transcutaneous electrical nerve stimulators. The basic unit characteristics and output specifications of the two devices are summarized in the tables below.

Basic Unit Characteristics.

Parameter	NeuroMetrix SENSUS	Empi Active Transcutaneous Nerve Stimulator (K090922)
510(k) Number	(to be assigned)	K090922
Device Name and Model Number	SENSUS	Active Transcutaneous Nerve Stimulator
Manufacturer	NeuroMetrix	Empi
Power Source(s)	1 rechargeable 3.7V Lithium-Ion battery	1 rechargeable battery (type unknown)
Method of Line Current Isolation	Physically isolated; device cannot connect to electrodes and battery recharger concurrently	Physically isolated; device cannot connect to electrodes and battery recharger concurrently
Patient Leakage Current		
Normal Condition	< 10 µA, battery powered	Unknown
Single Fault Condition	< 100 µA, battery powered	Unknown
Average DC current through electrodes when device is on but no	< 1 µA	Unknown

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pulse are being applied (μA)			
Number of Output Modes		1	1
Number of output channels	Synchronous or alternating	1	1
	Method of channel isolation	N/A	N/A
Regulated Current or Regulated Voltage		Current	Nominally constant voltage in the positive phase, nominally constant current in the negative phase
Software/Firmware/Microprocessor Control		Yes	Yes
Automatic Overload Trip?		Yes	No
Automatic No-Load Trip?		Yes	No
Automatic Shut Off?		Yes after timer elapses	Yes if left at 0 mA for 5 minutes
User Override Control?		Yes, press STIM button	Yes, press POWER button
Indicator Display:	On/Off Status?	Yes, upon pressing STIM button	Yes, status LED flashes when on
	Low Battery?	Yes	Yes
	Voltage/Current Level?	No	No
Timer Range		60 minutes	N/A
Compliance with Voluntary Standards		IEC 60601-1 IEC 60601-1-2	IEC 60601-1-2 UL 60601-01 CAN/CSA C22.2 No.601.1-M90 with Amendment A2.2005
Compliance with 21 CFR 898		Yes	Yes
Weight		95g (3.4 oz)	0.99 oz
Dimensions (W x H x D)		22mm (0.9") x 66mm (2.6") x108mm (4.3")	0.57"x1.94"x2.54"
Housing Materials & Construction		Plastic	Plastic

Output Specifications.

Parameter		NeuroMetrix SENSUS	Empi Active Transcutaneous Nerve Stimulator (K090922)
Mode or Program Name		N/A	N/A
Waveform		Biphasic	Biphasic
Shape (output current)		Rectangular	Approximately rectangular initial phase, slowly decaying second phase
Maximum Output Voltage (10 +/- %)		50 V @500 Ω 100 V @2000 Ω 100 V @10000 Ω	25 V @500 Ω 35 V @2000 Ω 39 V @10000 Ω
Maximum Output Current (10 +/- %)		100 mA @500 Ω 50 mA @2000 Ω 10 mA @10000 Ω	50 mA @500 Ω 18 mA @2000 Ω 4 mA @10000 Ω
Duration of primary (depolarizing) phase		100 μs	400 μs at maximum intensity
Pulse Duration (both phases)		230 μs, includes 30 μs inter-phase delay	Approximately 1 msec, exact duration unspecified due to slowly decaying second phase
Frequency		Constant, 80 Hz	Modulated, 2-125 Hz
For multiphasic	Symmetrical phases	Yes	No

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waveforms only:	Phase Duration	100 µs (each phase)	400 µs (initial phase), at maximum intensity
Net Charge (per pulse)		Nominally 0 µC @ 500Ω, zero net current	Nominally 0 µC because pulse shape is described as balanced
Maximum Phase Charge		10 µC @ 500Ω 10 µC @ 1000Ω	17 µC @ 500Ω 10 µC @ 1000Ω
Maximum Current Density (r.m.s.)		0.63 mA/cm^2 @ 500Ω	1.73 mA/cm^2 @ 500Ω
Maximum Average Current		1.6 mA @ 500 Ω	10 mA @ 500Ω
Maximum Average Power Density		4 mW/cm^2 @ 500Ω	8 mW/cm^2 @ 500Ω
Burst Mode	Pulses per burst	N/A	N/A
	Bursts per second	N/A	N/A
	Burst duration	N/A	N/A
	Duty Cycle	N/A	N/A
ON Time		N/A	N/A
OFF Time		N/A	N/A
Additional Features		N/A	N/A

The primary differences between the two devices relate to the output specifications, specifically the (i) pulse waveform shape and duration, (ii) maximum output voltage and maximum output current, and (iii) pulse pattern.

(i) Pulse waveform shape and duration: SENSUS generates a symmetrical biphasic rectangular output current pulse while ACTIVE generates a balanced asymmetrical biphasic pulse with the initial phase approximately rectangular and a slowly decaying second phase. The SENSUS pulse duration is fixed at 100 µsec per phase while the initial phase of the ACTIVE pulse duration varies with the intensity setting, and the overall duration is approximately 1000 µsec. Because the physiological effectiveness of nerve stimulation is primarily dependent on charge delivered, either pulse waveform shape will be effective. Therefore this difference does not raise new types of questions of safety or effectiveness.

(ii) Maximum output voltage and maximum output current: SENSUS has a higher maximum output voltage than ACTIVE (50 V for SENSUS versus 25V for ACTIVE into a 500Ω load). SENSUS also has a higher maximum output current, i.e, 100 mA as compared to 50 mA in ACTIVE (500Ω load). Because the SENSUS pulse duration is shorter and the charge delivered per pulse is titrated by the patient, the maximum charge per pulse is similar for the two devices. Therefore this difference does not raise new types of questions of safety or effectiveness.

(iii) Pulse pattern: SENSUS stimulates with a fixed duration pulse at a constant frequency of 80 Hz while ACTIVE stimulates with pulses that automatically cycle through a range of durations and frequencies between 2 and 125 Hz. This difference between SENSUS and ACTIVE does not raise new types of safety or effectiveness questions because (i) neither device gives the patient control over frequency, (ii) both devices are using standard TENS stimulation frequencies, (iii) constant frequency stimulation is standard practice, and (iv) the clinical effectiveness of transcutaneous electrical nerve stimulation for chronic intractable pain is not dependent on the use of modulated pulse trains such as those generated by ACTIVE, and can be achieved through either constant or modulated frequency and duration.

SENSUS and the predicate device have similar types of control over stimulation intensity, with minor differences in the specific user interaction sequences. These differences do not raise new types of safety or effectiveness questions because in both devices the (i) stimulation intensity is under patient control such that he/she can change the intensity, stop further intensity increases, and halt stimulation

at any time and (ii) the stimulation intensity always starts at 0 mA and increases gradually, smoothly and predictably, thereby avoiding the risk of sudden changes in intensity that may startle the patient.

In sum, SENSUS and the predicate have the same intended use and the only technological differences relate to several output specifications and aspects of intensity control. As discussed above, these differences in technological characteristics are relatively minor and do not raise new types of safety or effectiveness questions and do not adversely affect the safety and effectiveness of the SENSUS device compared to the predicate. As a result, the SENSUS device is substantially equivalent to the predicate ACTIVE device.

GUIDANCE DOCUMENT

The FDA's "Draft Guidance for Industry and Staff: Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief (April 5, 2010)" addresses transcutaneous electrical nerve stimulators with product code GZJ. The recommendations from the draft guidance were taken into account in preparing this 510(k) submission. NeuroMetrix believes that SENSUS complies with the special controls as outlined in the draft guidance, thereby providing additional assurance of safe and effective use of the SENSUS device.

NON-CLINICAL TESTING

Verification testing of SENSUS includes electrical, mechanical, and software tests to show that the device meets its target specifications over a range of operating and storage conditions. Validation and performance testing demonstrates that it meets user needs as reflected in the functional specification.

SENSUS conforms to the following voluntary standards:

- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance 2005 (3rd Ed) plus Amendments 1:2006 and 2:2007
- IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2007)
- IEC 60601-1-6 Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral standard: Usability (3rd Ed) 2010-1
- IEC 62304:2006 Medical device software – Software life cycle processes

CLINICAL TESTING

NeuroMetrix determined that non-clinical (i.e., bench) testing was sufficient to demonstrate that SENSUS is as safe and effective as the predicate.

CONCLUSION

The verification, validation and performance data presented in this 510(k) submission demonstrate that the NeuroMetrix SENSUS device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 2 2012

NeuroMetrix, Inc.
c/o Mr. Rainer Maas
Director of QA/RA
62 Fourth Ave.
Waltham, MA 02451

Re: K121184
Trade/Device Name: SENSUS
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: July 23, 2012
Received: July 24, 2012

Dear Mr. Maas:

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 Part 801); 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 Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K121184

Device Name: NeuroMetrix SENSUS

Indications for Use:

The NeuroMetrix SENSUS is intended for use as a transcutaneous electric nerve stimulation device for the symptomatic relief and management of chronic intractable pain.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K121184