K130919

JUL 0 2 2013

510(k) Summary
for
NeuroMetrix SENSUS™

SPONSOR

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Date Prepared: March 31, 2013

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

NeuroMetrix SENSUS (K121184)

INTENDED 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.

The device may be used during sleep. The device is labeled for use only with the NeuroMetrix SENSUS Electrode.

DEVICE DESCRIPTION

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

The device delivers electrical stimulation to the patient through disposable, single-patient use electrodes placed on the patient's body. The device is labeled for use only with the SENSUS Electrode (K121816), to which it connects through insulated female medical snap connectors embedded within its housing.

The device has a push-button that initiates stimulation, halts stimulation, and controls the intensity. The device has a single two color LED for indication of stimulation status, battery charging, and error conditions.

COMPARISON TO PREDICATE

The SENSUS device subject to this submission is a modification of the predicate SENSUS device (K121184). The two tables below provide a comparison of basic unit characteristics and output specifications.

Basic Unit Characteristics

Parameter		Modified SENSUS	Predicate SENSUS
510(k) Number			K121184
Device Name and Model Number		Same	SENSUS
Manufacturer		Same	NeuroMetrix
Power Source(s)		Same	1 rechargeable 3.7V Lithium-Ion battery
Method of Line Current Isolation		Same	Physically isolated; device cannot connect to electrodes and battery recharger concurrently
Patient Leakage Current			
Normal Condition		Same	< 10 µA, battery powered
Single Fault Condition		Same	< 100 µA, battery powered
Average DC current through electrodes when device is on but no pulse are being applied (µA)		Same	< 1 µA
Number of Output Modes		Same	1
Number of output channels	Synchronous or alternating	Same	1
	Method of channel isolation	Same	N/A
Regulated Current or Regulated Voltage		Same	Current
Software/Firmware/Microprocessor Control		Same	Yes
Automatic Overload Trip?		Same	Yes
Automatic No-Load Trip?		Same	Yes
Automatic Shut Off?		Same	Yes, after timer elapses or on trip condition
User Override Control?		Same	Yes, press button
Indicator Display:	On/Off Status?	Same	Yes, upon pressing button
	Low Battery?	Same	Yes
	Voltage/Current Level?	Same	No
Timer Range		Same	60 minutes
Compliance with Voluntary Standards		Same	IEC 60601-1 IEC 60601-1-2
Compliance with 21 CFR 898		Same	Yes
Weight		82g (2.9 oz)	95g (3.4 oz)
Dimensions (W x H x D)		18mm (0.7") x 63mm (2.5") x176mm (6.9")	22mm (0.9") x 66mm (2.6") x108mm (4.3")
Housing Materials & Construction		Plastic, Velcro® straps (Nylon)	Plastic

Output Specifications

Parameter		Modified SENSUS	Predicate SENSUS
Mode or Program Name		Same	N/A
Waveform		Same	Biphasic
Shape (output current)		Same	Rectangular
Maximum Output Voltage (10 +/- %)		Same	50 V @500 Ω 100 V @2000 Ω 100 V @10000 Ω
Maximum Output Current (10 +/- %)		Same	100 mA @500 Ω 50 mA @2000 Ω 10 mA @10000 Ω
Duration of primary (depolarizing) phase		Same	100 µs
Pulse Duration (both phases)		Same	230 µs, includes 30 µs inter-phase delay
Frequency		Random, mean 80 Hz, uniform distribution 60 - 100 Hz	Constant, 80 Hz
For multiphasic waveforms only:	Symmetrical phases	Same	Yes
	Phase Duration	Same	100 µs (each phase)
Net Charge (per pulse)		Same	Nominally 0 µC @ 500Ω, zero net current
Maximum Phase Charge		Same	10 µC @ 500Ω 10 µC @ 1000Ω
Maximum Current Density (r.m.s.)		0.51 mA/cm^2 @ 500Ω	0.63 mA/cm^2 @ 500Ω
Maximum Average Current		Same	1.6 mA @ 500 Ω
Maximum Average Power Density		3.6 mW/cm^2 @ 500Ω	4 mW/cm^2 @ 500Ω
Burst Mode	Pulses per burst	Same	N/A
	Bursts per second	Same	N/A
	Burst duration	Same	N/A
	Duty Cycle	Same	N/A
ON Time		Same	N/A
OFF Time		Same	N/A
Additional Features		Same	N/A

The modified and predicate devices have similar technological characteristics, and testing shows that any differences in technology do not raise new types of safety or effectiveness questions, and that the modified device is at least as safe and effective as the predicate device. The modified device incorporates minor dimensional and technological changes, as summarized below.

- The modified device has slightly different weight and physical dimensions, and comes with a Velcro® strap for attachment to a patient's leg.

- The modified device stimulates with a random frequency instead of a fixed frequency. The mean frequency (80 Hz) of the modified device is the same as the fixed frequency of the predicate, and the range of frequencies (60-100 Hz) are within the range typically used with transcutaneous electrical nerve stimulators.

- The modified device has lower maximum current density and maximum average power density because it is labeled for use only with the SENSUS Electrode (K121816), which has a minimum electrode area of 28 cm^2 as compared to the minimum electrode area of 20 cm^2 at which the predicate device was specified.

- The modified device disables manual control over intensity if the push-button has not been pressed for three minutes. A light slap to the device enclosure, detected by an embedded accelerometer, re-enables manual control over intensity.

- The modified device includes a procedure by which the device determines the patient's sensation threshold from which the starting intensity for subsequent therapy sessions is determined.

In addition to these minor technological changes, the modified device incorporates two labeling changes relating to: (1) removing the warning against use during sleep, and (2) specifying the particular type of electrode (SENSUS Electrode) for use with the device.

The modified device is intended for use during wakefulness and during sleep. The labeling (User Manual) for the predicate device includes a warning against using the device during sleep. The modified device differs from the predicate in that it includes safety features that make the warning superfluous. As a result, the User Manual was revised to delete the sleep warning, consistent with the technological changes. The use of the modified SENSUS transcutaneous electrical nerve stimulator during sleep does not raise new types of safety or effectiveness questions because the question, i.e., whether the device delivers safe and clinically effective electrical stimulation to the patient, is the same as for the predicate device. Testing demonstrated that the addition of safety features adequately addresses any potential safety risks associated with using the device during sleep; therefore, the removal of the warning from the labeling does not adversely affect the safety or effectiveness of the modified device compared to the predicate.

The modified device includes mechanical safety mechanisms to prevent electrode peeling and, if it occurs, a trip condition to halt stimulation. As noted above, the device is only labeled for use with the SENSUS Electrode. This electrode utilizes a self adhesive hydrogel that should not be prone to spontaneous peeling. The device is attached to the patient's leg with a Velcro® strap that encircles the electrode and thereby secures and protects it. The practical likelihood that these two mechanical safety mechanisms fail in a sleeping patient and lead to a dangerous level of electrode peeling is low.

To address any residual potential hazard, the modified device halts stimulation before the electrode to skin contact area decreases to 3.5 cm^2, which is an 8-fold reduction from the minimum electrode area of 28 cm^2. Therefore, the maximum current density and maximum average power density are assured of being less than 4 mA/cm^2 and 28.5 mW/cm^2, respectively. These current and power density levels, while elevated compared to normal operating parameters of the modified device with a SENSUS Electrode completely on the skin, are comparable to previously cleared devices that include transcutaneous electrical nerve stimulation functionality (21 CFR 882.5890, product code GZJ) such as K121059, K121305, and K080950. Furthermore, the maximum average power density is substantially below the 250 mW/cm^2 threshold identified as increasing the risk of thermal burns in 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)." NeuroMetrix conducted validation testing of this safety mechanism, and the results that are included in this submission demonstrate that the modified device, which is indicated for use during wakefulness and sleep, is at least as safe and effective as the predicate device.

While the predicate device is labeled for use with any legally available electrode that meets certain specifications, the modified device is labeled for use with only one of the electrodes currently used in the predicate, the SENSUS Electrode (K121816). This use specification, in part, ensures the safe use of the device during sleep because the SENSUS Electrode has highly adhesive hydrogel pads and a known surface area that allows the SENSUS device to reliably determine relative peeling and decrease in skin contact area (see discussion of safety feature above). Because the SENSUS Electrode is a legally

marketed electrode intended for use as an interface between the patient's skin and a transcutaneous electrical nerve stimulator, and is currently used with the SENSUS device, specifying use of the SENSUS device with only the SENSUS Electrode does not change the 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 the modified SENSUS device complies with the special controls as outlined in the draft guidance, thereby providing additional assurance of safe and effective use of the modified SENSUS device. As discussed above, the modified device's labeling does not include the recommended warning not to apply stimulation while the patient is sleeping because the modified device incorporates safety features that mitigate any potential risks associated with using the device during sleep.

VALIDATION OF ELECTRODE PEELING DETECTION

In support of labeling the device for use during sleep, NeuroMetrix validated the function that halts stimulation when the device detects that the electrode has peeled. A detection failure was defined as failing to halt stimulation when the remaining skin contact area of the peeling electrode was less than 3.5 cm^2. The prospective validation sample size was set to 60 tests and the primary acceptance criterion was a failure rate of 0%. At this failure rate level (i.e., 0 out of 60 tests), the upper bound of the one-sided 95% confidence interval was 4.9% which indicates a 95% confidence that the true failure rate was below 5%. The lower bound of all two-sided confidence intervals includes a true failure rate of 0%.

Two instances of the validation protocol were run. The difference between the two runs was the duration of time the SENSUS Electrode was left on the skin prior to initiating electrode peeling. In one run it was 10 minutes and in the other it was 40 minutes. In each run, 66 tests were conducted, each with a different subject and SENSUS Electrode to maintain statistical independence. The hydrogel on the SENSUS Electrodes was stressed to mimic prior use of the electrodes.

The same 66 subjects were used in the two protocol runs, but a different SENSUS Electrode was used in each test; therefore a total of 132 SENSUS Electrodes were evaluated. Each test used a randomly chosen electrode peel rate. At the beginning of a test, the SENSUS Electrode was placed on the subject and a therapy session was initiated. After 10 or 40 minutes, depending on the protocol run, the outer electrode was peeled away from the skin at the designated peel rate. The electrode area remaining on the skin at the instant when stimulation halted was logged. A test failure was defined as a remaining contact area less than 3.5 cm^2.

The average remaining electrode contact area detected by the modified device was 10.2 ± 2.1 cm^2 (range 6.9 – 19.5 cm^2) for the 10 minute run and 10.1 ± 1.7 cm^2 (range 7.5 – 18.0 cm^2) for the 40 minute run. There were 0 failures among the 66 tests in both protocol runs. On the basis of these results, detection of electrode peeling was validated.

NON-CLINICAL TESTING

Verification testing of the modified device 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 the modified device meets user needs as reflected in the functional specification.

The modified SENSUS device conforms to the following 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 bench and non-clinical testing was sufficient to demonstrate that the modified SENSUS device is as safe and effective as the predicate SENSUS device.

CONCLUSION

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

July 2, 2013

NeuroMetrix, Inc.
% Rainer Maas
62 Fourth Avenue
Waltham, MA 02451

Re: K130919
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: April 1, 2013
Received: April 3, 2013

Dear Rainer 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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130919

Device Name: 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.

The device may be used during sleep. The device is labeled for use only with the NeuroMetrix SENSUS Electrode.

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)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number _K130919_____