JUL 0 3 2014

K140333

510(k) Summary
for
ASCEND™

SPONSOR

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Contact Person: Rainer Maas
Telephone: (781) 314-2781
Date Prepared: February 7, 2014

DEVICE NAME

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

PREDICATE DEVICE

NeuroMetrix SENSUS (K130919)
PDI Works Pain-Aid (K113037)

INTENDED USE

ASCEND is intended for use as a transcutaneous electrical nerve stimulation device for temporary relief of pain associated with sore and aching muscles in the lower extremities due to strain from exercise or normal household and work activities.

ASCEND is intended for use as a transcutaneous electrical 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 compatible NeuroMetrix electrodes.

DEVICE DESCRIPTION

ASCEND is a single output-mode transcutaneous electrical nerve stimulator for symptomatic relief and management of chronic intractable pain that is available over the counter. The device utilizes a microprocessor running embedded software to control a high-voltage circuit that generates current-regulated stimulating pulses with specific technical characteristics including pulse shape, amplitude, duration, pattern, and frequency. The device is powered by an embedded rechargeable Lithium-Ion battery that is charged through a USB cable connected to an AC adapter.

The device delivers electrical stimulation to the user through disposable electrodes placed on the user's body. The device is labeled for use only with compatible NeuroMetrix electrodes (e.g, SENSUS Electrode, K121816), to which it connects through insulated female medical snap connectors embedded within its housing; no lead-wires are used. Compatible NeuroMetrix electrodes are comprised of four

individual hydrogel pads arranged in a linear array. The hydrogel pads are electrically connected in pairs such that the two outer hydrogel pads constitute one electrode and the two inner hydrogel pads constitute a second electrode. The user interface consists of a push button and a two-color LED. The push button initiates and controls stimulation intensity. The LED indicates stimulation status, battery charging, and error conditions.

COMPARISON TO PREDICATES

ASCEND has similar indications for use and identical technological characteristics as the cleared SENSUS device (K130919). The only substantive difference is that ASCEND is labeled for over-the-counter use while SENSUS is labeled for prescription use. The over-the-counter labeling is based on the substantial equivalence of ASCEND to PDI Works Pain-Aid (K113037), a transcutaneous electrical nerve stimulator labeled for over-the-counter use and sold without a prescription. In further support of over-the-counter labeling, this submission includes results from a prospective usability study that demonstrates the safe and effective use of ASCEND, as labeled, in the intended population.

Comparison of Indications for Use

As stated above, ASCEND has the similar indications for use as the cleared SENSUS device *i.e.*, both are intended for use as a transcutaneous electric nerve stimulation device for the symptomatic relief and management of chronic intractable pain, and may be used during sleep. The table below compares ASCEND, SENSUS and Pain-Aid indications for use. All three devices are indicated for the symptomatic relief and management of chronic intractable pain.

Comparison of Indications for Use.

NeuroMetrix ASCEND	NeuroMetrix SENSUS (K130919)	PDI Works Pain-Aid (K113037)
ASCEND is intended for use as a transcutaneous electrical nerve stimulation device for temporary relief of pain associated with sore and aching muscles in the lower extremities due to strain from exercise or normal household and work activities. ASCEND is intended for use as a transcutaneous electrical 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 compatible NeuroMetrix electrodes.	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	To be used for temporary relief of pain associated with sore and aching muscles in the upper and lower back, and upper and lower extremities due to strain from exercise or normal household and work activities. To be used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

Comparison of Technological Characteristics

ASCEND and SENSUS have identical technological characteristics. ASCEND and Pain-Aid have the same basic technological characteristics as listed below.

- One stimulation channel
- Single output mode
- Patient controlled intensity
- Fixed therapy session timer
- LED indicator (no intensity display)
- Powered by battery

Both ASCEND and Pain-Aid have output specifications that are within the range of other FDA cleared transcutaneous electrical nerve stimulators. In the case of ASCEND, the basic unit characteristics and output specifications are identical to those of the SENSUS device, which FDA recently cleared through its 510(k) review process (K130919); i.e., it is the same device. The basic unit characteristics and output specifications of ASCEND, SENSUS and Pain-Aid are summarized in the tables below.

There are no technical differences between ASCEND and SENSUS. The primary technical differences between ASCEND and Pain-Aid are the (i) pulse waveform shape and duration, (ii) maximum output current, (iii) pulse pattern, and (iv) trip conditions.

(i) Pulse waveform shape and duration: ASCEND generates a symmetrical biphasic rectangular output current pulse. Pain-Aid generates an asymmetrical biphasic pulse with the initial phase rectangular. The ASCEND pulse duration is fixed at 100 μsec per phase while the initial phase of the Pain-Aid pulse duration is modulated between 30 and 220 μsec. Because the physiological effectiveness of nerve stimulation is dependent on total charge delivered, the shape of the pulse waveform does not impact device's effectiveness. In other words, either pulse waveform shape is effective. Therefore this difference does not raise new types of questions of safety or effectiveness.

(ii) Maximum output current: ASCEND has a higher maximum output current; 100 mA as compared to 63 mA in Pain-Aid. Because the charge delivered per pulse is set by the patient to a strong but comfortable sensation, the charge delivered is therapeutically effective with either device. Furthermore, ASCEND has the same maximum output current as the predicate SENSUS device. Therefore, this difference does not raise new types of questions of safety or effectiveness.

(iii) Pulse pattern: ASCEND stimulates with a fixed duration pulse at a randomly varying frequency between 60 and 100 HZ with mean 80 Hz. Pain-Aid stimulates with pulses that cycle through a range of durations and frequencies between 2 and 100 Hz. This difference between ASCEND and Pain-Aid 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) random frequency stimulation is within the standard practice for TENS devices and is used in the predicate SENSUS device, 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 Pain-Aid, and can be equally achieved through random frequency stimulation as delivered by ASCEND.

(iv) Trip conditions: ASCEND has trip conditions not found in Pain-Aid. These include detection of over-load, no-load, insufficient charge, high impedance, and short circuit conditions. Detection of any of these immediately halts stimulation. ASCEND also includes an electrode peeling trip condition that addresses the potential hazard of electrode peeling during sleep. These trip conditions enhance the safety of ASCEND compared to Pain-Aid and therefore this difference does not raise new types of questions of safety or effectiveness.

Basic Unit Characteristics.

Parameter		NeuroMetrix ASCEND	NeuroMetrix SENSUS	PDI Works Pain-Aid
510(k) Number		(to be assigned)	K130919	K113037
Device Name and Model Number		ASCEND	SENSUS	Pain-Aid
Manufacturer		NeuroMetrix	NeuroMetrix	PDI Works
Power Source(s)		3.7V Lithium-Ion battery (rechargeable)	3.7V Lithium-Ion battery (rechargeable)	3V Lithium battery (non-rechargeable)
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	Non-rechargeable, no connection to line current
Patient Leakage Current				
Normal Condition		Battery powered (< 10 µA)	Battery powered (< 10 µA)	Battery powered
Single Fault Condition		Battery powered (< 100 µA)	Battery powered (< 100 µA)	Battery powered
Average DC current through electrodes when device is on but no stimulation		< 1 µA	< 1 µA	Information not available
Number of Output Modes		1	1	1
Number of output channels	Synchronous or alternating	1	1	1
	Method of channel isolation	N/A	N/A	N/A
Regulated Current or Regulated Voltage		Current	Current	Current
Software/Firmware/Microprocessor Control		Yes	Yes	Yes
Automatic Overload Trip?		Yes	Yes	No
Automatic No-Load Trip?		Yes	Yes	No
Automatic Shut Off?		Yes, after timer elapses or on trip condition	Yes, after timer elapses or on trip condition	Yes, after timer elapses
User Override Control?		Yes	Yes	No
Indicator Display:	On/Off Status?	Yes	Yes	Yes
	Low Battery?	Yes	Yes	No
	Voltage/Current Level?	No	No	No
Timer Range		60 minutes	60 minutes	30 minutes
Compliance with Voluntary Standards		IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2
Compliance with 21 CFR 898		Yes	Yes	Yes
Weight		82g	82g	20 g
Dimensions (W x H x D)		176mm x 63mm x 18mm	176mm x 63mm x 18mm	64mm x 38mm x 13mm
Housing Materials & Construction		Plastic, Velcro® straps (Nylon)	Plastic, Velcro® straps (Nylon)	Plastic

Output Specifications.

Parameter		NeuroMetrix ASCEND	NeuroMetrix SENSUS	PDI Works Pain-Aid (K113037)
Mode or Program Name		N/A	N/A	N/A
Waveform		Biphasic, Symmetrical	Biphasic, Symmetrical	Biphasic, Asymmetrical
Shape (output current)		Rectangular	Rectangular	Rectangular
Maximum Output Voltage (10 +/- %)		50 V @500 Ω 100 V @2000 Ω 100 V @10000 Ω	50 V @500 Ω 100 V @2000 Ω 100 V @10000 Ω	Information not available
Maximum Output Current (10 +/- %)		100 mA @500 Ω 50 mA @2000 Ω 10 mA @10000 Ω	100 mA @500 Ω 50 mA @2000 Ω 10 mA @10000 Ω	63 mA @500 Ω
Duration of primary (depolarizing) phase		100 µs	100 µs	30 – 220 µs (modulated)
Pulse Duration (both phases)		200 µs, additional 30 µs inter-phase delay	200 µs, additional 30 µs inter-phase delay	Information not available
Frequency		Random, mean 80 Hz, uniform distribution 60 - 100 Hz	Random, mean 80 Hz, uniform distribution 60 - 100 Hz	2 – 100 Hz (modulated)
For multiphasic waveforms only:	Symmetrical phases	Yes	Yes	No
	Phase Duration	100 µs (each phase)	100 µs (each phase)	30 -220 µs (depolarizing phase, modulated)
Net Charge (per pulse)		Nominally 0 µC @ 500Ω, zero net current	Nominally 0 µC @ 500Ω, zero net current	Information not available
Maximum Phase Charge		10 µC @ 500Ω 10 µC @ 1000Ω	10 µC @ 500Ω 10 µC @ 1000Ω	Information not available
Maximum Current Density (r.m.s.)		0.51 mA/cm^2 @ 500Ω	0.51 mA/cm^2 @ 500Ω	Information not available
Maximum Average Current		1.6 mA @ 500 Ω	1.6 mA @ 500 Ω	Information not available
Maximum Average Power Density		3.6 mW/cm^2 @ 500Ω	3.6 mW/cm^2 @ 500Ω	Information not available
Burst Mode	Pulses per burst	N/A	N/A	N/A
	Bursts per second	N/A	N/A	N/A
	Burst duration	N/A	N/A	N/A
	Duty Cycle	N/A	N/A	N/A
ON Time		N/A	N/A	N/A
OFF Time		N/A	N/A	N/A
Additional Features		N/A	N/A	N/A

Comparison of Usability Characteristics

ASCEND and SENSUS have identical usability characteristics. ASCEND and Pain-Aid have easy-to-use controls that support their over-the-counter use without a prescription. The primary differences between the devices are the number of push buttons used to control the device and the primary mode of setting the therapeutic intensity. ASCEND uses short and long button press sequences to accomplish the same control functions with 1 button for which Pain-Aid uses 3 buttons. This difference is a convenience that does not raise new types of safety or effectiveness questions. ASCEND offers a configuration procedure whereby the therapeutic intensity is determined from the user's sensation threshold. This function provides a convenient way to set the intensity within the expected therapeutic window. Once set through configuration, the intensity can be manually adjusted up or down. Pain-Aid does not provide a similar configuration procedure; the user must set the therapeutic intensity manually. This difference between

the devices is one of convenience. Because both devices allow for manual adjustment, ASCEND's additional convenience feature does not raise new types of safety or effectiveness questions.

Summary

ASCEND has identical indications for use and technological characteristics as the cleared SENSUS device, and the only difference is that ASCEND is labeled for over-the-counter use. Usability testing discussed below shows this difference has no safety or effectiveness significance. ASCEND and Pain-Aid have unit characteristics and output specifications that are within the range of legally-marketed transcutaneous electrical nerve stimulators. Both devices are indicated for symptomatic relief and management of chronic intractable pain and have similar usability characteristics. The differences between the two devices do not raise new types of safety or effectiveness questions. As a result, ASCEND is substantially equivalent to SENSUS and Pain-Aid.

USABILITY STUDY

The objective of the usability study was to validate that previously untrained users can operate ASCEND in a safe and effective manner based on their reading and following of the directions for use contained in the device labeling without the supervision or assistance of a medical professional. Specifically, the usability study examined labeling consisting of an instructional video and quick start instructions. These materials cover five basic device tasks: checking battery, placing device and configuring, starting a therapy session, modifying stimulation intensity, and stopping a therapy session. The acceptance criterion was that at least 80% of participants successfully completed all five tasks.

A total of 29 participants were enrolled, all of which completed the study. No significant usability issues were identified. The percentage of participants completing all five tasks successfully was 86.2% (95% CI, 68.3 – 96.1), i.e., 25 of 29 participants. The upper bound of the 95% confidence interval (96.1%) exceeded 80%, and therefore the null hypothesis that the true pass rate was $\geq$ 80% could not be rejected. Because the prospective study criterion was met, the usability study achieved its primary objective of validating that untrained users could operate the device in a safe and effective manner based on their reading and following of the directions for use contained in the device labeling without the supervision or assistance of a medical professional. Therefore the usability study results support the safe and effective use of ASCEND, as labeled, in the intended population.

GUIDANCE DOCUMENT

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

NON-CLINICAL TESTING

Verification testing of the ASCEND 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, performance, and usability testing demonstrates that the device meets user needs as reflected in the functional specification.

ASCEND 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, usability and non-clinical testing were sufficient to demonstrate that ASCEND is as safe and effective as the predicate SENSUS and Pain-Aid devices.

CONCLUSION

The verification, validation, performance, and usability data presented in this 510(k) submission demonstrate that ASCEND is substantially equivalent to the predicate SENSUS and Pain-Aid devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 3, 2014

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

Re: K140333
Trade/Device Name: ASCEND
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: May 30, 2014
Received: June 2, 2014

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 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" (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,

Felipe Aguel -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140333

Device Name
ASCEND

Indications for Use *(Describe)*
ASCEND is intended for use as a transcutaneous electrical nerve stimulation device for temporary relief of pain associated with sore and aching muscles in the lower extremities due to strain from exercise or normal household and work activities.

ASCEND is intended for use as a transcutaneous electrical 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 compatible NeuroMetrix electrodes.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.07.03 17:21:37 -04'00'

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