



Food and Drug Administration
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July 23, 2016

SPR Therapeutics, LLC
c/o Susan Alpert, Ph.D., M.D.
Consultant, SF A Consulting, LLC
200 Park Avenue, Unit 111
Minneapolis, MN 55415

Re: K161154

Trade/Device Name: Smartpatch PNS System
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator
Regulatory Class: Class II
Product Code: NHI
Dated: April 22, 2016
Received: April 25, 2016

Dear Dr. Alpert:

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 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,

William J. Heetderks

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Digitally signed by William J. Heetderks - A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH,
ou=People, 0.9.2342.19200300.100.1.1=0010149848,
cn=William J. Heetderks - A
Date: 2016.07.23 15:57:16 -0400

for Carlos L. Peña, Ph.D., M.S.

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)

K161154

Device Name

Smartpatch Peripheral Nerve Stimulation (PNS) System

Indications for Use (Describe)

The Smartpatch Peripheral Nerve Stimulation (PNS) System is indicated for up to 30 days in the back and/or extremities for:

- Symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain;
- Symptomatic relief of post-traumatic pain;
- Symptomatic relief of post-operative pain.

The Smartpatch PNS System is not intended to treat pain in the craniofacial region.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

1. SUBMITTER

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216-378-9116 (fax)

Contact Person: Susan Alpert, PhD, MD, Consultant
Telephone: 612-202-7019

Date Prepared: June 24, 2016

2. DEVICE

Trade/Proprietary Name: Smartpatch PNS System
Common/Usual Name: Peripheral Nerve Stimulator
Classification Name: Percutaneous Electrical Nerve Stimulation (PENS)
devices (21 CFR 882.5890)
Regulatory Class: II
Product Codes: NHI

3. PREDICATE DEVICE

BiowavePENS System (K052289, K061166, K072123, K152437)

Reference devices: Vertis Percutaneous Neuromodulation Therapy (PNT)
(K011702, K022241), St. Jude/ANS Quattrode Lead (K991784, K000852)

4. DEVICE DESCRIPTION

The Smartpatch PNS System is comprised of a percutaneous electrode placed via an introducer needle in proximity to a target peripheral nerve associated with a painful area and a wearable external stimulator that delivers stimulation therapy to the percutaneous electrode. The Smartpatch PNS System provides peripheral nerve stimulation (PNS) therapy to relieve pain. The percutaneous electrode is a sterile, flexible, coiled, stainless steel wire designed to be percutaneously inserted through the skin via an introducer needle and remain indwelling for the duration of the therapy (up to 30 days). The diameter of the wire is 0.26mm. The wire is

provided in two lengths (20cm, 40cm) with a maximum placement depth of approximately 10cm.

5. INDICATIONS FOR USE

The Smartpatch Peripheral Nerve Stimulation (PNS) System is indicated for up to 30 days in the back and/or extremities for:

- Symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain;
- Symptomatic relief of post-traumatic pain;
- Symptomatic relief of post-operative pain.

The Smartpatch PNS System is not intended to treat pain in the craniofacial region.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The determination of substantial equivalence is based on comparison of the indications for use, operational characteristics, and fundamental technological characteristics of the BiowavePENS System and the Smartpatch PNS System. The Smartpatch PNS System has equivalent indications for use and technical characteristics to the BiowavePENS System and other Class II Percutaneous Electrical Nerve Stimulation (PENS) Devices. Another similar device is the Vertis Percutaneous Neuromodulation Therapy (PNT) (K011702, K022241), which is included as a reference device. These devices consist of electrodes placed percutaneously in proximity to a painful area, an external stimulator, and associated tools and accessories intended to deliver peripheral nerve stimulation for the symptomatic relief of pain.

A side-by-side comparison of the characteristics of the Smartpatch PNS System, the cited predicate device (BiowavePENS and BiowaveHOME), and the reference device (Vertis Percutaneous Neuromodulation Therapy) is provided in Tables 1 and 2 and discussed below.

Table 1 Side-by-Side Comparison: Smartpatch PNS Stimulator vs. BiowavePENS Stimulator (cited predicate) vs. Vertis PNT (reference device)

Feature/ Characteristic	Smartpatch PNS Stimulator	BiowavePENS Stimulator K061166 (Predicate device)	Vertis PNT K011702 K022241 (Reference device)
<i>Intended Use/Indications for Use</i>			
Indications for Use	The Smartpatch Peripheral Nerve Stimulation (PNS) System is indicated for up to 30 days in the back and/or extremities for: <ul style="list-style-type: none"> • Symptomatic relief of chronic, intractable pain, post surgical and post-traumatic acute pain; • Symptomatic relief of post-traumatic pain; • Symptomatic relief of post-operative pain. 	The Deepwave Percutaneous Neuromodulation Pain Therapy System is comprised of a percutaneous electrode array and the Deepwave Neuromodulation Pain Therapy Device. The Deepwave Neuromodulation Pain Therapy System is indicated for: <ul style="list-style-type: none"> • Symptomatic relief of chronic, intractable pain, post surgical and post-traumatic acute pain; • Symptomatic relief of post-traumatic pain; • Symptomatic relief of post-operative pain. 	Percutaneous Neuromodulation Therapy (PNT) is indicated for the symptomatic relief and management of chronic or intractable pain and/or as an adjunctive treatment in the management of post-surgical pain and post-trauma pain. The PNT Control Unit is to be used with PNT Lumbar Safeguides for low back pain or PNT Cervical Safeguides for neck and/or upper back pain.
Prescription (Rx) device	Yes	Yes	Yes
Intended for use in clinical environment	Yes	Yes	Yes
Intended for use in patient home environment	Yes	Yes (BiowaveHOME)	No
Single use electrodes	Yes	Yes	Yes
Patient exposure <30 days (Non-implant)	Yes	Yes	Yes
Portable/body-worn components	Yes	Yes	No
<i>Stimulation</i>			

Feature/ Characteristic	Smartpatch PNS Stimulator	BiowavePENS Stimulator K061166 (Predicate device)	Vertis PNT K011702 K022241 (Reference device)
Amplitude range, mA volts p-p	0.2-20 0-30	UNK 0-27.5 rms	0-151 UNK
Stimulating phase, maximum duration, μ sec	200	130 (feed frequency)	200
Frequency, Hz	5-100	122 (beat frequency)	4-50
Duty cycle, %	50 or 100	100	UNK
Stimulation between separately placed cathode & anode	Yes	Yes	Yes
Waveform	Biphasic rectangular with a positive and negative phase that is charge balanced	Biphasic sine waves with a positive and negative phase that is charge balanced	Biphasic rectangular with a positive and negative phase that is charge balanced
Pulse Generator			
Software/ Firmware/ Microprocessor Control	Yes	Yes	Yes
Weight	.024 kg	.45 kg	3.18kg
Size	Hand-held	Hand-held	Desktop
Number of channels	1	1	5
Location	External	External	External
Software-driven	Yes	Yes	Yes
Power Source	Battery Powered External Stimulator w/replaceable batteries	Battery Powered External Stimulator w/rechargeable batteries	Line Power

1 Percutaneous electrical nerve stimulation has also been delivered at 25mA. 1. Rozen, D. and G.W. Grass, *Intradiscal electrothermal coagulation and percutaneous neuromodulation therapy in the treatment of discogenic low back pain*. Pain practice : the official journal of World Institute of Pain, 2005. 5(3): p. 228-43.

Feature/ Characteristic	Smartpatch PNS Stimulator	BiowavePENS Stimulator K061166 (Predicate device)	Vertis PNT K011702 K022241 (Reference device)
Patient isolated	Yes	Yes	Yes
Features			
On/off activation	Button	Button	Button
Text prompts	On LCD screen	On LCD screen	On LCD screen
Intensity control	Plus and minus buttons used to increase therapy to strong but comfortable level	Plus and minus buttons used to increase therapy to strong but comfortable level	Knob and buttons used to increase therapy to strong but comfortable level
Data recording	Yes (e.g. usage time, parameters, error codes)	Yes (e.g. usage time, parameters, error codes)	UNK

UNK = Not able to determine from publicly available materials. FDA may have access to information in cleared 510(k)s.

Table 2 Side-by-Side Comparison: Smartpatch percutaneous electrode vs. BiowavePENS percutaneous electrode (cited predicate) vs. Vertis PNT (reference device)

Feature/ Characteristic	Smartpatch percutaneous electrode	BiowavePENS percutaneous electrode K061166 (Predicate device)	Vertis PNT K011702 K022241 (Reference device)
Introduction method	Percutaneous	Percutaneous	Percutaneous
Tissue contact	Skin/tissue	Skin/tissue	Skin/tissue
Electrode type	Percutaneous fine wire	Percutaneous fine needle	Percutaneous fine needle
Stimulating electrode material	316L Stainless Steel	316L Stainless Steel	Stainless Steel
Maximum charge density at electrode	0.4 μ C/mm ²	UNK	0.2 μ C/mm ²
Stimulating electrode shape	Straight with tine	Straight	Straight

Feature/ Characteristic	Smartpatch percutaneous electrode	BiowavePENS percutaneous electrode K061166 (Predicate device)	Vertis PNT K011702 K022241 (Reference device)
Electrode configuration	1 pair (1 percutaneous electrode and 1 surface electrode)	1 pair (1 percutaneous set of 1014 electrodes and 1 surface electrode)	5 pairs (each pair consists of two percutaneous electrodes)
Diameter of percutaneous extension	635µm (0.025 inches (outer diameter of coiled wire))	UNK	250µm
Electrode length	15.2mm (lead is either 20cm or 40cm with 10cm introducer needle)	0.74mm	UNK (surface area 16mm ²)
Supplied sterile	Yes	Yes	Yes

UNK = Not able to determine from publicly available materials. FDA may have access to information in cleared 510(k)s.

The Smartpatch PNS System uses the same fundamental technologies as the BiowavePENS System and other Class II PENS devices such as the reference Vertis PNT device. Like the BiowavePENS System and Vertis PNT, the Smartpatch PNS System is intended to be a prescription (Rx) device for use by or on the order of a licensed healthcare practitioner. In all three Systems, low levels of electrical current are delivered by an external stimulator through electrodes that are placed percutaneously in proximity to a target peripheral nerve associated with a painful area. In all three devices, short-term electrical stimulation therapy is delivered for symptomatic relief and management of pain.

There are two minor technological differences; the electrode configuration and the stimulation waveform. The BiowavePENS percutaneous needle array electrodes are used for a single 30-minute treatment and then discarded, with a new set of needles inserted for each treatment session. The flexible Smartpatch percutaneous electrode design enables the electrode to be percutaneously placed once and left in place to deliver therapy at home as prescribed, and discarded at the end of the therapy. This minor difference in electrode configuration does not raise any new types of questions of safety and effectiveness, as both designs pass through the skin, dwell in place for the treatment sessions, and safely deliver electrical stimulation for the desired short-term treatment period. Of note, the Vertis PNT percutaneous electrodes are straight needles passing through the skin to a depth of approximately 2-4cm, consistent with the placement of the Smartpatch percutaneous electrodes.

The Biowave, Vertis and Smartpatch external stimulators deliver biphasic

electrical stimulation waveforms with a positive and negative phase that is charge balanced between an active percutaneous electrode and a return surface electrode to activate peripheral nerves and relieve pain. The Vertis PNT and Smartpatch PNS Systems deliver rectangular waveforms with an adjustable frequency, pulse duration, and intensity. The BiowavePENS delivers sine waveforms also with an adjustable intensity. The intensity of the Vertis PNT and Smartpatch PNS System stimulation waveforms is adjusted by changing current intensity, while the intensity of the BiowavePENS stimulation waveform is adjusted by changing voltage intensity. These minor differences do not raise new questions of safety and effectiveness.

Based on the information available for these devices, on thorough verification and validation testing, and on support of safety from clinical studies, SPR has established the substantial equivalence of the Smartpatch PNS System to the cited predicate device. SPR has demonstrated that the Smartpatch PNS System has substantially equivalent technical characteristics to the BiowavePENS device. Further, the minor technological differences between the devices do not raise new questions regarding safety and effectiveness, and evaluation of the effect of the technological differences supports the finding of substantial equivalence.

7. PERFORMANCE DATA

Nonclinical testing of this device includes biocompatibility testing, electrical testing (safety and electromagnetic compatibility), system performance testing, and software verification and validation.

Although no effectiveness data are required to demonstrate substantial equivalence, clinical testing includes multiple completed and ongoing studies on chronic or intractable pain, post-surgical pain, and post-traumatic pain. These studies have demonstrated safety of the therapy. The adverse events reported in the studies included skin irritation, erythema, a blister, or a mild skin tear. The majority of the adverse events were resolved with little to no intervention and resolved within a few days, and none were classified as serious.

A randomized controlled trial failed to show that the Smartpatch was effective for post-stroke shoulder pain.

8. CONCLUSIONS

The Smartpatch PNS System has been shown through comparison to be substantially equivalent to the identified predicate device.