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

June 26, 2017

SPR Therapeutics, LLC
Kathryn Stager
Manager of Regulatory Affairs
22901 Millcreek Blvd., Suite 110
Cleveland, Ohio 44122

Re: K170902
Trade/Device Name: Sprint System, Single Procedure Kit, Sprint System with Pad II, Single Procedure Kit, Sprint System, Multi-Procedure Kit, Sprint System, Sterile Components Kit, Sprint System, Stimulator Kit
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NHI
Dated: March 28, 2017
Received: March 28, 2017

Dear Kathryn Stager:

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" (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 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 -S
2017.06.26 13:39:09 -04'00'

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)*
K170902

Device Name
SPRINT Peripheral Nerve Stimulation (PNS) System

Indications for Use *(Describe)*
The SPRINT Peripheral Nerve Stimulation (PNS) System is indicated for up to 60 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 SPRINT 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1. SUBMITTER

SPR Therapeutics, LLC
22901 Millcreek Boulevard, Suite 110
Cleveland, OH 44122

216-378-9108 (phone)
216-378-9116 (fax)

Contact Person: Kathryn Stager, MS, RAC, Manager of Regulatory Affairs
Telephone: 216-378-9067

Date Prepared: March 28, 2017

2. DEVICE

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

3. PREDICATE DEVICE

Smartpatch PNS System (K161154)*

4. DEVICE DESCRIPTION

The Sprint 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 Sprint PNS System provides peripheral nerve stimulation (PNS) therapy to relieve pain. The percutaneous electrode is a sterile,

* The Smartpatch PNS System is presently being marketed under the name Sprint PNS System as reported in K161154/A001. The name Smartpatch is being used in this 510(k) application for clarity.

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 60 days).

5. COMPARISON OF INDICATIONS FOR USE WITH THE PREDICATE DEVICE

Indications Statement:
The SPRINT Peripheral Nerve Stimulation (PNS) System is indicated for up to 60 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 SPRINT PNS System is not intended to treat pain in the craniofacial region.

Comparison:
This indications statement is identical to the Smartpatch PNS System cleared in K161154 except that the duration of therapy was extended from 30 days to 60 days. Extending the treatment period to an upper limit of 60 days does not result in a new intended use when compared to the predicate device. In contrast to treatment periods longer than 60 days, this extension to an upper limit of 60 days does not raise different safety and effectiveness questions because the device, like the predicate device, is intended to provide treatment for the pain conditions specified in the indications statement (e.g., post-traumatic pain, post-operative pain) using a limited duration of therapy.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The purpose of this 510(k) is to obtain clearance for a change in the indication for use statement. The Sprint PNS System has the same technological characteristics as the Smartpatch PNS System. No changes have been made to the physical components of the system since clearance of K161154 other than:

- elimination of the longer lead length (clinical experience has revealed that it provides no increased utility compared to the shorter lead, as the introducer needle is the same length),
- elimination of the lead connector tapes (clinical experience has revealed that they provide no increased utility compared to commercially available bandages), and
- addition of a Pad that has a larger battery capacity (25mAhr compared to

14mAhr) to reduce the frequency at which Pads need to be replaced.

These minor modifications to the Smartpatch PNS System are intended to result in a simpler and easier to use product for the end-users (called the Sprint PNS System). They do not raise new questions regarding safety and effectiveness.

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.

Clinical data was provided in K170902 to establish safety and effectiveness for extension of use (as per the IFU) of the SPRINT PNS system from 30 to 60 days. Clinical testing on the subject device 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.

In addition to the clinical data provided in K170902, clinical experience from other electrical stimulation devices intended for the relief of pain, which deliver the same electrical stimulation therapy, demonstrates that there are no different or increased risks resulting from the long-term use of electrical stimulation for pain. Therefore, extending the treatment period to 60 days also does not raise different questions of effectiveness than the predicate or significantly increase an effectiveness concern.

8. CONCLUSIONS

The Sprint PNS System has been shown to be substantially equivalent to the identified predicate device.