January 22, 2021

SPR Therapeutics, Inc.
Kathryn Stager
Director of Regulatory Affairs and Quality Systems
22901 Millcreek Blvd. Suite 110
Cleveland, Ohio 44122

Re: K202660
Trade/Device Name: SPRINT PNS System
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NHI
Dated: December 22, 2020
Received: December 23, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

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.

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"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, Inc
22901 Millcreek Boulevard, Suite 110
Cleveland, OH 44122

216-378-9108 (phone)
216-674-2303 (fax)

Contact Person: Kathryn Stager, MS, RAC, Director of Regulatory Affairs & Quality Systems
Telephone: 216-378-9067

Date Prepared: September 10, 2020

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

SPRINT PNS System (K181422)

4. DEVICE DESCRIPTION

The SPRINT PNS System is comprised of one or two percutaneous electrodes placed via introducer needles in proximity to target peripheral nerves associated with a painful area and a wearable external Pulse Generator (stimulator) that delivers stimulation therapy to the percutaneous electrode(s). The SPRINT PNS System provides peripheral nerve stimulation (PNS) therapy to relieve pain. The percutaneous electrode (MicroLead) is a sterile, flexible, coiled, stainless steel wire designed to be percutaneously inserted and remain indwelling for the duration of the therapy (up to 60 days). The Pulse Generator and accessory components provide tools for percutaneous MicroLead placement, system programming by the clinician, and system use by the patient.

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:
The indication for use statement is identical to that cleared in K181422.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

SPR has made some design modifications to the SPRINT® PNS System to improve ease of use and reliability of the system. None of the changes affect the intended use or fundamental functionality of the device.

The key modifications include the following:

- The frequency range is being expanded and finer adjustment of duty cycle and session duration will be permitted by the clinician.
- Two new cables are being introduced to simplify the MicroLead placement procedure.
- The shelf life for sterile components is being extended from 12 months to 24 months.
- An additional hydrogel formulation for the Mounting Pad is being made available for patients with skin sensitivity.

None of these changes alters the fundamental delivery of peripheral nerve stimulation to the target nerve(s) through the identical MicroLead electrode, using the identical stimulus waveform, limited by the identical charge delivery, for the identical indications for use.

7. PERFORMANCE DATA

Nonclinical testing of this device includes biocompatibility testing, electrical testing (safety and electromagnetic compatibility), software verification and validation, system performance testing, human factors/usability testing, and sterile package integrity testing.

8. CONCLUSIONS

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