January 25, 2023

SPR Therapeutics, Inc.
Kathryn Stager, MS, RAC
Vice President of Regulatory Affairs and Quality Systems
22901 Millcreek Blvd. Suite 500
Cleveland, Ohio 44122

Re: K223306
Trade/Device Name: SPRINT Peripheral Nerve Stimulation (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: October 26, 2022
Received: October 27, 2022

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,

Lauren E. Woodard -S

for Amber Ballard, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223306

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 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 be placed in the region innervated by the cranial and facial nerves.

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, Inc
22901 Millcreek Boulevard, Suite 500
Cleveland, OH 44122
216-378-9108 (phone)
216-674-2303 (fax)

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

Date Prepared: January 25, 2023

2. DEVICE

Trade/Proprietary Name:	SPRINT Peripheral Nerve Stimulation (PNS) System
Common/Usual Name:	Peripheral Nerve Stimulator
Regulation Name:	Transcutaneous electrical nerve stimulator for pain relief
Regulation Number:	21 CFR 882.5890
Regulatory Class:	II
Product Code:	NHI

3. PREDICATE DEVICE

SPRINT PNS System (K211801)

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.

The therapeutic benefit of PNS is mediated via the activation of sensory fibers, such as muscle proprioceptive afferents, which drive afferent mediated mechanisms at the spinal and/or supraspinal level. At the level of the spinal cord, gate-control mechanisms provide pain relief. Stimulation of large, myelinated afferents is thought to inhibit the

transmission of pain signals from the spinal cord to higher centers in the central nervous system to decrease the perception of pain, as described by Melzack and Wall's gate-control theory. Stimulation of peripheral sensory afferents is believed to "close the gate" by decreasing the relay of pain signals via cells in the spinothalamic tract (STT), one of the primary pain pathways. Activation of these non-nociceptive afferent fibers for pain relief can be accomplished by direct stimulation of the afferent nerves or by evoking comfortable muscle contractions, which in turn activate sensory afferents.

In addition, there is now growing evidence that chronic pain is associated with changes at the supraspinal level that maintain the pain experience even when the causative factors are no longer active or are less severe. There is also evidence that cortical plasticity related to chronic pain can be modified by behavioral interventions that provide feedback to the brain areas that were altered by somatosensory pain memories. Thus, it is possible that afferent activation due to peripheral nerve stimulation alters the pain experience. The plausibility of this hypothesis is supported by studies that demonstrate that electrical stimulation is a powerful modality for providing feedback to the central nervous system with resultant neuroplastic changes. A recent publication[1] describes Peripherally-Induced Reconditioning of the Central Nervous System (CNS) as a new theory for the mechanism for treating pain using neuromodulation. This theory may explain why pain relief can be sustained after the treatment is complete.

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 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 be placed in the region innervated by the cranial and facial nerves.

Comparison:
The indication for use statement is identical to that cleared in K211801 with the exception of a wording change in the last sentence that is intended to increase clarity for prescribing physicians (i.e., "be placed" was previously "treat pain").

[1] Deer, T. R. *et al.* Peripherally Induced Reconditioning of the Central Nervous System: A Proposed Mechanistic Theory for Sustained Relief of Chronic Pain with Percutaneous Peripheral Nerve Stimulation. *J Pain Res* **14**, 721-736, doi:10.2147/JPR.S297091 (2021).

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:

- ***Introduction of a new system configuration called the Conversion Kit.*** The Conversion Kit does not introduce any new components or change the treatment being provided. It is a new sales configuration that allows a patient to receive a second lead if they start their 60-day treatment period with a single lead but their physician later decides a second lead is medically necessary. If the patient receives a single-lead system and then a Conversion Kit, it is no different than receiving a dual-lead system.
- ***Introduction of new external system components to make lead securement easier to achieve.*** This includes the addition of a breakaway connection (intended to reduce the risk of force being inadvertently applied to the lead) and additional desinsulating contact points on the MicroLead Connector to improve the reliability of the connection.

These changes, and the other minor changes described throughout, do not alter the fundamental delivery of peripheral nerve stimulation to the target nerve(s) using the identical stimulus waveform and limited by the identical charge delivery. Therefore, these changes do not affect the safety or effectiveness of the subject device. Refer to Table 1 for a comparison of technological characteristics.

Table 1 Comparison of Technological Characteristics

Feature/Characteristic	**Subject Device: SPRINT PNS**	**Predicate: SPRINT PNS (K211801)**
System Configurations		
Single Lead Dual Lead Conversion Kit	Yes Yes Yes	Same Same No
Stimulation Therapy		
Amplitude range, mA volts p-p	 0.2-30 0-45	 Same Same
Stimulating phase, duration range, µsec	10-200	Same
Frequency, Hz	5-150	Same
Duty cycle, %	<1-100	Same

Stimulation between separately placed cathode & anode	Yes	Same
Waveform	Charge Balanced Asymmetric Biphasic	Same
Treatment Session Duration, hours	1-24	Same
Physical Components		
Software/Firmware/ Microprocessor Control	Yes	Same
Number of channels	2	Same
Weight of pulse generator	.030 kg	Same
Location	External body worn	Same
Indicators	Color LED and audible on Pulse Generator; LCD display on Hand-Held Remote	Same
Intensity control	Plus and minus buttons on Hand-Held Remote	Same
Pulse Generator Battery Type	Lithium Ion Polymer Rechargeable Battery	Same
Pulse Generator, Rechargeable Battery and Remote Housing Material	ABS Plastic	Same
Percutaneous Lead		
Introduction method	Percutaneous	Same
Tissue contact	Skin/tissue	Same
Materials	316L Stainless Steel, Silicone, PFA	Same
Electrode configuration	1-2 percutaneous fine wire electrodes and 1 surface return electrode	Same
Electrode length	15 mm	Same
Electrode shape	Straight with anchor	Same

Anchor configuration	Straight (not coiled) wire	Same
Number of strands	19	Same
Lead length	221mm	Same
Supplied sterile	Yes (EO sterilization)	Same
Maximum duration of implant	60 days	Same
Introducer System		
Hypodermic Lead Introducer Gauge Wall thickness Length	 20 gauge Extra thin wall 12.5cm long	 Same Same Same
Materials	Polycarbonate, 304 Stainless Steel, Parylene Coating	Same
Test stimulation delivery	Stimulating Probe loaded in Percutaneous Sleeve inserted in target location	Same
Gauge of insertion needle	20 gauge (Introducer) or 17 gauge (Sleeve)	Same
Percutaneous fine wire electrode (MicroLead) placement	Pre-loaded in Introducer, placed through Percutaneous Sleeve after stimulation with Stimulating Probe	Same
Lead Securement Components and Patient Cabling		
Materials	ABS Plastic, thermoplastic polyester elastomer, PVC	Same
Additional Breakaway Connection	Yes	No
Deinsulating Contact Points	4	2
Mounting Pads		
Provided Sterile/Non-Sterile	Sterile: 9619-10B, 9619-KM40C Non-Sterile: 9618-63B, 9618-40C	Sterile: 9619-10B Non-Sterile: 9618, 9618-63B, 9618-40C

7. NONCLINICAL PERFORMANCE TESTING

Updated nonclinical testing of the subject device includes biocompatibility testing per the standards listed in Table 2.

Table 2 Applicable Standards

Standard Number	Title
ISO 10993-5	Biological Evaluation Of Medical Devices - Part 5: Tests for in vitro cytotoxicity, 2009
ISO 10993-6	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation, 2016
ISO 10993-7	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals, 2008-10-15 [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)]
ISO 10993-18	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process, 2020

Moreover, the subject device conforms to all applicable standards associated with electrical testing (safety and electromagnetic compatibility), software verification and validation, system performance testing, human factors, sterility, biocompatibility, and magnetic resonance compatibility, which were leveraged from the previously cleared predicate device (K211801).

8. CLINICAL PERFORMANCE DATA

The bench and non-clinical performance testing support the substantial equivalence of this device. No clinical performance data were included in support of this submission.

9. CONCLUSIONS

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