



October 13, 2021

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

Re: K211801

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: September 9, 2021
Received: September 10, 2021

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,

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

Indications for Use

510(k) Number (if known)
K211801

Device Name
SPRINT PNS System

Indications for Use (Describe)

The SPRINT 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 treat pain 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.

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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, Vice President of Regulatory Affairs & Quality Systems
Telephone: 216-378-9067

Date Prepared: October 12, 2021

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

Primary: SPRINT PNS System (K202660)
Secondary: Biowave Deepwave System (K061166)

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 publication¹ 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 treat pain in the region innervated by the cranial and facial nerves.

Comparison:

The indication for use statement is similar to that cleared in K202660 but removes the restriction that it be used "in the back and/or extremities" and clarifies the statement about use to stimulate cranial and facial nerves.

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:

- The design of the MicroLead is being modified to strengthen it.
- The tray that contains the Pulse Generator, Rechargeable Battery, Hand-Held Remote, and Mounting Pads is now provided sterile instead of non-sterile.

These changes do not alter the fundamental delivery of peripheral nerve stimulation to the target nerve(s) using the identical stimulus waveform, limited by the identical charge delivery, for the same intended 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, magnetic resonance compatibility testing, and sterile package integrity testing.

Product complaint data collected for the primary predicate device in accordance with 21 CFR Part 820.198 were provided. Product complaint data from 5,518 patients using the SPRINT PNS System commercially were analyzed and revealed a 6.2% rate of adverse events. Most adverse events were categorized as skin irritation, painful/uncomfortable stimulation, pain at the lead exit site, or minor infection resolved with antibiotics. The vast majority of adverse events were non-serious in nature, with 4 of the 341 events being classified as serious (these were submitted to the FDA as Medical Device Reports; reference 3011035812-2020-00001, 3011035812-2021-00002, 3011035812-2021-00003, and 3011035812-2021-00004). The rate of adverse events was consistent across regions of the body in which the SPRINT PNS System was used. These data indicate use of this device in accordance with its Indications for Use would be as safe as the predicate device. Data on effectiveness were not provided and therefore the FDA has not assessed the effectiveness of the device in specific regions.

8. CONCLUSIONS

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