



January 2, 2021

Spark Biomedical, Inc.
% Michelle Rubin-Onur
Senior Regulatory Specialist
AcKnowledge Regulatory Strategies, LLC
2251 San Diego Avenue, Suite B-257
San Diego, California 92110

Re: K201873

Trade/Device Name: Sparrow Therapy System
Regulation Number: 21 CFR 882.5896
Regulation Name: Percutaneous Nerve Stimulator For Substance Use Disorders
Regulatory Class: Class II
Product Code: PZR
Dated: October 2, 2020
Received: October 5, 2020

Dear Michelle Rubin-Onur:

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/pmnmn.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

Indications for Use

510(k) Number (if known)
K201873

Device Name
Sparrow Therapy System

Indications for Use (Describe)

The Sparrow is a transcutaneous nerve field stimulator that is intended to be used in patients experiencing opioid withdrawal in conjunction with standard symptomatic medications and other therapies for opioid withdrawal symptoms under the supervision of trained clinical personnel.

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
PRASStaff@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 K201873

DATE PREPARED

January 2, 2020

MANUFACTURER AND 510(k) OWNER

Spark Biomedical, Inc.
18208 Preston Road, Ste D9-531
Dallas, TX 75252
Telephone: (877) 546-7727
Official Contact: Daniel Powell, CEO

REPRESENTATIVE/CONSULTANT

Michelle Rubin-Onur, Ph.D.
Allison C. Komiyama, Ph.D., R.A.C.
AcKnowledge Regulatory Strategies, LLC
Telephone: +1 (619) 458-9547
Email: mrubin@acknowledge-rs.com
Website: <https://www.acknowledge-rs.com/>

DEVICE INFORMATION

Proprietary Name/Trade Name: Sparrow Therapy System
Common Name: Percutaneous Nerve Stimulator For Opioid Withdrawal
Classification Name: Percutaneous nerve stimulator for substance use disorders
Regulation Number: 21 CFR 882.5896
Class: Class II
Product Code: PZR
Premarket Review: Neurology
Review Panel: Neurological Devices

PREDICATE DEVICE IDENTIFICATION

Sparrow Therapy System is substantially equivalent to the following predicate:

<i>Submission Number</i>	<i>Predicate Device Name / Manufacturer</i>	<i>Primary Predicate</i>
DEN170018	NSS-2 Bridge / Innovative Health Solutions (IHS), Inc.	✓

The predicate device has not been subject to a design related recall.



510(k) Summary

DEVICE DESCRIPTION

The Sparrow Therapy System is a non-invasive, battery-operated, prescription device designed to transcutaneously stimulate nerves on and/or around the auricle to be used in patients experiencing opioid withdrawal in conjunction with standard symptomatic medications and other therapies for opioid withdrawal symptoms under the supervision of trained clinical personnel. The system includes three components: Earpiece, Patient Controller, and the Clinician Application. Sparrow is used in clinical environments (i.e., rehab centers and hospitals) and at home. Users of the subject device include experiencing opioid withdrawal symptoms.

INDICATIONS FOR USE

The Sparrow is a transcutaneous nerve field stimulator that is intended to be used in patients experiencing opioid withdrawal in conjunction with standard symptomatic medications and other therapies for opioid withdrawal symptoms under the supervision of trained clinical personnel.

CHARACTERIZATION OF OPIOID WITHDRAWAL SYMPTOMS

Opioid withdrawal symptoms occur when chronic users who are dependent on opioids suddenly reduce or stop using opioids. Opioid addiction is a national crisis and physical symptoms of opioid withdrawal can be one of the biggest barriers for patients seeking help and ultimately overcoming addiction. The fear of experiencing withdrawal symptoms often prevents those suffering from opioid addiction from seeking help. And those who seek assistance may relapse due to continued withdrawal symptoms.

Signs and symptoms of opioid withdrawal include lacrimation or rhinorrhea, piloerection (goose flesh), myalgia, diarrhea, nausea/vomiting, pupillary dilation and photophobia, insomnia, autonomic hyperactivity (i.e., tachycardia, sweating, hypertension, and hyperthermia), and yawning. Currently, the standard of care for opioid withdrawal symptoms is done using pharmacological management. The primary predicate device, a percutaneous nerve field stimulator (PNFS) system, has also been used as an aid to reduce the symptoms of opioid withdrawal, through application to branches of Cranial Nerves V, VII, IX and X, and the occipital nerves identified by transillumination.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Spark Biomedical believes that the Sparrow Therapy System is substantially equivalent to the predicate device based on the information summarized here:

The subject device has the same intended use and similar technological characteristics as the device granted in DEN170018. Unlike the device granted in DEN170018, the subject device is designed to deliver the stimulation transcutaneously rather than percutaneously. Therefore, the subject device does not have needles that penetrate intact skin. Overall, the Sparrow Therapy System has undergone non-clinical and clinical testing to ensure that any difference in technological characteristics (i.e., design and stimulation parameters) do not affect safety and effectiveness when compared to the predicate device.

510(k) Summary

	<i>Subject Device</i>	<i>Primary Predicate</i>	<i>Justification for differences</i>
Indications for Use	The Sparrow is a transcutaneous nerve field stimulator that is intended to be used in patients experiencing opioid withdrawal in conjunction with standard symptomatic medications and other therapies for opioid withdrawal symptoms under the supervision of trained clinical personnel.	The NSS-2 BRIDGE is a percutaneous nerve field stimulator (PNFS) system, that can be used as an aid to reduce the symptoms of opioid withdrawal, through application to branches of Cranial Nerves V, VII, IX and X, and the occipital nerves identified by transillumination.	Both devices are intended to be used as an aid to patients experiencing opioid withdrawal symptoms. Delivery method for stimulation is different (transcutaneous vs percutaneous) and the placement of the subject device does not require transillumination. These differences have been shown to be acceptable based on non-clinical data, clinical data and a benefit-risk assessment.
Maximum Voltage (V)	2.5 @ 500 Ω 10 @ 2K Ω 50 @ 10K Ω	3.2 @ 500 Ω 3.2 @ 2K Ω 3.2 @ 10K Ω	The differences in the output values are based on the delivery method for stimulation (transcutaneous vs percutaneous). These differences have been shown to be acceptable based on non-clinical data and clinical data.
Maximum Current (mA)	5.0 @ 500 Ω 5.0 @ 2K Ω 5.0 @ 10K Ω	6.4 @ 500 Ω 1.6 @ 2K Ω 0.32 @ 10K Ω	
Maximum Pulse Width (μs)	750	1000	
Maximum Frequency (Hz)	150	10	

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Sparrow Therapy System. However, the submission demonstrated compliance to the Special Controls per 21 CFR 882.5896. The following tests were performed to demonstrate safety based on current industry standards:

Biocompatibility

Patient contacting material was subjected to biocompatibility testing in compliance to:

- ISO 10993-1 *Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process*
- ISO 10993-5 *Biological Evaluation Of Medical Devices — Part 5: Tests For In Vitro Cytotoxicity*

510(k) Summary

- ISO 10993-10 *Biological Evaluation Of Medical Devices — Part 10: Tests For Irritation And Skin Sensitization*

Software Verification

The software development and testing was executed in compliance to:

- IEC 62304 *Medical Device Software — Software Lifecycle Processes*
- ISO 14971 *Medical Devices - Application Of Risk Management To Medical Devices*

Electromagnetic Compatibility and Electrical Safety

The subject device was tested in compliance to:

- ANSI/AAMI 60601-1 *Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD) (Consolidated Text) (Includes ANSI/AAMI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012)*
- ANSI/AAMI 60601-1-11 *Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment*
- ANSI/AAMI/IEC 60601-1-2 *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*
- IEC 60601-2-10 *Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators*

SUMMARY OF CLINICAL TESTING

A double blind, randomized, prospective study, including a group with delayed treatment, was designed to assess the effectiveness of the Sparrow Therapy System. The study evaluated transcutaneous nerve stimulation (tAN) as a method to aid in the reduction of symptoms associated with opioid withdrawal.

The patient population included male and female participants, aged 18-65 with a history of dependence on prescriptive or non-prescriptive opioids (n=26). Subjects were enrolled at one US site based on 90% power at alpha 0.05 for detecting a mean (+SD) reduction in clinical opiate withdrawal scale (COWS) of 17 (+7) points when compared to baseline values.

In brief, study participants were randomized in a 1:1 ratio to one of two groups:

1. active transcutaneous auricular neurostimulation (tAN) + usual treatment or
2. delayed-active tAN + usual treatment

Participants in the active tAN group received tAN immediately whereas those in the delayed-active tAN had their therapy turned on after a delay (inactive period-first 30 minutes). All participants were informed of their group assignment at the conclusion of the randomized, double blind period and all continued to receive active tAN throughout the five-day study.

The primary effectiveness endpoint of this study was successful mean percent change in COWS

510(k) Summary

score (defined as a $\geq 15\%$ reduction) from baseline to 60 minutes after start of active tAN therapy.

The secondary endpoints of this study included:

- Comparison of mean percent change in COWS score in delayed active tAN versus active tAN groups at 30 minutes
- Comparison of the proportion of participants with a clinically significant reduction in COWS score (defined as a 15% or greater reduction) in delayed-active tAN versus active tAN groups at 30 minutes
- Mean percent change in COWS score from baseline to 30 minutes after start of active tAN therapy
- Mean percent change in COWS score from baseline to 120 minutes after start of active tAN therapy
- Mean percent change in COWS score from baseline to Days 2 through 5 after start of active tAN therapy

Safety Endpoints included the prevalence of all adverse events (AEs), serious adverse events (SAEs), adverse device events (ADEs), serious adverse device effects (SADEs), unanticipated serious adverse device effects (USADEs), and device deficiencies.

Of the 26 subjects enrolled in the study, 14 completed the study. The study results for all subjects including study completers and non-completers are listed below. Data from both the active tAN and the delayed-active tAN groups were pooled for the primary effectiveness analysis. The clinical study demonstrated that the subject device met the primary endpoint.

<i>Key Metric</i>	<i>All Subjects (N=26)</i>	<i>Study Completers (N=14)</i>
Percentage of patients who passed the naloxone challenge ¹	10/26 (38.5%)	10/14 (71.4%)
Percentage of patients completing the study	14/26 (53.8%)	---
COWS score percent reduction at 60 minutes	50.4%	50.5%
Percentage of patients transitioning to MAT	12/26 (46.2%)	7/14 (50.0%)

¹ The naloxone challenge was delivered if the subject UDS tested negative on Day 3 or Day 5. One subject did not pass the naloxone challenge at Day 3 and withdrew from the study. Among the 14 study completers, 10 completed the naloxone challenge, two on Day 3, and eight on Day 5. Four additional subjects did not participate in the challenge on Day 5 as they tested positive for opioids on the UDS and were no longer eligible due to risk of precipitated withdrawal.

510(k) Summary

The 12 subjects that did not complete the study had numerous reasons for early withdrawal. These reasons are listed below.

<i>Reason</i>	<i>Number of Participants</i>
Patients had a clinically meaningful reduction in COWS (symptom improvement) but decided to continue treatment with an opioid-based medication <ol style="list-style-type: none"> Participant COWS score was reduced from a baseline score of 13 to a score of 4 at 60 minutes (69.2% reduction). Participant COWS score was reduced from a baseline score of 16 to a score of 11 at 60 minutes (31.3% reduction). 	2
Left detox facility against medical advice (AMA) <ol style="list-style-type: none"> Participant COWS score was reduced from a baseline score of 16 to a score of 8 at last assessment prior to leaving the detox treatment facility, which was at 60 minutes (50% reduction). Participant COWS score was reduced from baseline score of 14 to a score of 7 at 60 minutes (50% reduction) and a score of 7 at 120 minutes, the last assessment prior to leaving the detox treatment facility. Participant COWS score was reduced from a baseline score of 21 to a score of 10 at last assessment prior to leaving the detox treatment facility, which was at 60 minutes (52.4% reduction). 	3
Subject broke patient controller	1
Frustration with use of device <ol style="list-style-type: none"> Related to Bluetooth connectivity (Sparrow Therapy System application and firmware have resolved Bluetooth connectivity issue). 	1
Device deficiency	1
Adverse Event (precipitated withdrawal due to naloxone challenge)	1
Non-responder to therapy	2
Protocol non-compliance <ol style="list-style-type: none"> Subject was discovered with opioid based medication which broke protocol. Subject was removed from the study but not from the treatment facility. 	1
TOTAL	12

Results of the Patient Blinding Assessment showed that blinding was not able to be maintained despite adherence to all protocol procedures. This result is likely due to the initial perception of electrical stimulation during device programming, which provided a familiar sensation in line with the participant's expectation during active tAN.

SUMMARY OF THE BENEFIT-RISK ASSESSMENT

The FDA Guidance Document, “Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics,” issued September 25, 2018 was used in this substantial equivalence determination.

Subject demographics and baseline characteristics were similar to those reported in the decision summary reporting results from which the predicate device, the NSS-2 Bridge, was granted FDA clearance (DEN170018). In the publication, the average age at enrollment was 32.9 years, the proportion of male participants was 65% and the most commonly used opioid was heroin (68%). In the subject device study, the average age at enrollment was 35.5, the proportion of male participants was 65%, and the most commonly used opioid was heroin (89.5%) across all participants. In the NSS-2 Bridge study, the average baseline COWS score across all enrolled participants was 20.1 and the average baseline COWS score in the subject device study was 15.6. These values both correspond to moderate withdrawal symptoms. Also, similar to the NSS-2 Bridge study, most patients fell into the moderate withdrawal category (72.6% in the predicate device study compared to 95% in the subject device study).

The mean COWS score decreased from an average of 15.6 point at baseline to an average of 7.9 points at 60 minutes, demonstrating a mean reduction in the COWS score of 50.4% at 60 minutes (n=26). For the predicate device, the mean COWS score decreased from an average of 20.1 points at baseline to an average of 3.1 points at 60 minutes, demonstrating a mean reduction in the COWS score of 84.6% at 60 minutes (n=73). The Sparrow device did not demonstrate the same level of reduction in the COWS score at 60 minutes after treatment compared to the predicate device. The risk profiles for the Sparrow device and the predicate device are comparable, however, the use of transcutaneous nerve stimulation delivered through a non-invasive earpiece that does not puncture the skin, may present a lower risk of subcutaneous lesions, infection, or exposure to blood-borne pathogens (i.e., HIV or Hepatitis).

Other benefits of the Sparrow device include the use of an earpiece that is easy to apply and can be easily removed or replaced. The stimulation delivered by the subject device can be adjusted for comfort and tolerability. The user interface also allows for the user to easily tell whether stimulation is being delivered and whether therapy has stopped.

Based on this benefit-risk assessment, it was determined that the Sparrow device could be found substantially equivalent to the predicate device for the indication for use in patients experiencing opioid withdrawal in conjunction with standard symptomatic medications and other therapies for opioid withdrawal symptoms under the supervision of trained clinical personnel.



510(k) Summary

Spark Biomedical engaged 3S Consulting Group to perform an independent patient preference analysis. Seven individuals who have experienced opioid withdrawal were recruited and interviewed. None had any prior knowledge of the NSS-2 Bridge or Sparrow systems. All subjects (7/7) strongly preferred the Sparrow System noting two major reasons:

1. No needles
2. Ability to control stimulation intensity

CONCLUSION

Based on the non-clinical testing performed (i.e., biocompatibility, software verification, and EMC/electrical safety testing), and a clinical study, it can be concluded that the subject device does not raise concerns of safety or effectiveness compared to the predicate device. The similar indications for use, technological characteristics, and performance characteristics for the proposed Sparrow Therapy System along with utilizing the FDA Guidance Document, “Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics,” demonstrate the subject device is substantially equivalent to the predicate device.