June 20, 2023

Spark Biomedical, Inc.
% Allison Komiyama, PhD
VP of MedTech Innovation
Rqm+
2251 San Diego Avenue, Suite B-257
San Diego, California 92110

Re: K230796
Trade/Device Name: Sparrow Ascent
Regulation Number: 21 CFR 882.5896
Regulation Name: Percutaneous nerve stimulator for substance use disorders
Regulatory Class: Class II
Product Code: PZR
Dated: March 22, 2023
Received: March 22, 2023

Dear Dr Komiyama:

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,

Doe W. Kumsa -S (Affiliate)

Digitally signed by Doe W. Kumsa -S (Affiliate)
Date: 2023.06.20 17:44:49 -04'00'

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230796

Device Name
Sparrow Ascent

Indications for Use *(Describe)*
The Sparrow Ascent 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.

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510(k) Summary
K230796

DATE PREPARED
June 20, 2023

MANUFACTURER AND 510(k) OWNER
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DEVICE INFORMATION

Proprietary Name/Trade Name:	Sparrow Ascent
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:	Neurological and Physical Medicine Devices (OHT5) Neuromodulation and Rehabilitation Devices (DHT5B)
Review Panel:	Neurology

EXISTING DEVICE IDENTIFICATION
The Sparrow Ascent is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K201873	Sparrow Therapy System / Spark Biomedical, Inc.	✓

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

DEVICE DESCRIPTION
The Sparrow Ascent is a transcutaneous auricular neurostimulation (tAN) system intended to provide non-invasive, transcutaneous stimulation of the nerves on and/or around the auricle (ear). The device is indicated as an aid in the reduction of opioid withdrawal symptoms in adult patients.

510(k) Summary

The Sparrow Ascent is a battery operated, prescription device that delivers mild electrical stimulation to the nerves on and/or around the auricle (ear), which carry information to the central nervous system. The Sparrow Ascent is to be used in clinical environments (e.g., doctor's office, clinics, rehab centers, and hospitals) and/or at home. Users of the subject device include adults experiencing opioid withdrawal symptoms. Stimulation parameters (i.e., the strength of stimulation) are set by the user's clinician, and users can only adjust stimulation intensity at home. The system consists of three main components 1) a disposable Earpiece, 2) a Cable, and 3) the External Pulse Generator (EPG).

INDICATIONS FOR USE

The Sparrow Ascent 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.

COMPARISON OF INDICATIONS FOR USE STATEMENT

The Indications for Use statements of the subject device and the predicate device are identical. The intended use of both devices, to reduce the signs and symptoms associated with opioid withdrawal, is the same.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Spark Biomedical, Inc. believes that the Sparrow Ascent 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 cleared in K201873. Identical to the device cleared in K201873, the subject device is designed to deliver stimulation transcutaneously. The Sparrow Ascent has undergone non-clinical testing to ensure that any differences in technological characteristics (i.e., design) do not affect safety and effectiveness when compared to the predicate device. The Sparrow Ascent leverages prior clinical testing of the predicate device to help demonstrate effectiveness of the subject device.

	Subject Device	***Primary Predicate***	**Comparison**
Indications for Use	The Sparrow Ascent 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 Sparrow Therapy System 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.	Identical
Product Code / Regulation	PZR / 21 CF 882.5846	PZR / 21 CF 882.5846	Identical
Patient Population	Adult	Adult	Identical
Maximum Voltage (V)	2.5 @ 500 Ω 10 @ 2K Ω 50 @ 10K Ω	2.5 @ 500 Ω 10 @ 2K Ω 50 @ 10K Ω	Identical
Maximum Current (mA)	5.0 @ 500 Ω 5.0 @ 2K Ω 5.0 @ 10K Ω	5.0 @ 500 Ω 5.0 @ 2K Ω 5.0 @ 10K Ω	Identical
Maximum Pulse Width (µs)	750	750	Identical
Maximum Frequency (Hz)	150	150	Identical

SUMMARY OF NON-CLINICAL TESTING

The submission demonstrated compliance to the Special Controls per 21 CFR 882.5896. In addition to verification and validation testing of the Sparrow Ascent, the following tests were performed to support the clearance of K201873 and are applicable to the subject device.

Biocompatibility

- 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*
- ISO 10993-10 *Biological Evaluation Of Medical Devices — Part 10: Tests For Skin Sensitization*
- ISO 10993-23 *Biological Evaluation Of Medical Devices — Part 23: Tests For Irritation*
- Supportive information from the RESTORE clinical study (please refer to the Summary of Clinical Testing section below for information that supports biocompatibility of the Earpiece)

Software Verification

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

Electromagnetic Compatibility and Electrical Safety

- 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*

SUMMARY OF CLINICAL TESTING

Based on its technical performance and stimulation output data, no new clinical testing was required for the Sparrow Ascent. Clinical testing of the predicate device is summarized below.

A double blind, randomized, controlled, multi-center study 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. Subjects were enrolled at two US sites 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. At time of submission, a total of 23 participants were enrolled and 20 received tAN therapy. In brief, study participants were randomized in a 1:1 ratio to one of two groups:

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

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). 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 efficacy endpoint of this study was successful mean percent change in COWS score (defined as a ≥15% reduction) from baseline, 60 minutes after the start of active tAN therapy.

The secondary endpoints of the 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.

The clinical study demonstrated that the subject device met the primary endpoint. Subject demographics and baseline characteristics were similar to those reported in the publication

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. Similarly, 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).

Mean reduction in COWS score was 7.2 at 30 minutes and further reduced to 8.6 at 120 minutes. This reduction was further increased across days 2 through 5 with a 9.3-point reduction at Day 3 and a 13.1-point reduction at Day 5. The overall repeated measures ANOVA (RMANOVA) yielded significance and Bonferroni pairwise comparisons yielded significant differences at each time point when compared to baseline. At the conclusion of Day 1 (120 minutes), 93.8% of participants had a clinically significant reduction in COWS score. This increased to 100% on Day 2 and was sustained across Day 5. Therefore, the primary endpoint of this study (defined as a ≥15% reduction in COWS score) from baseline to 60 minutes after start of active tAN therapy was successfully met.

Spark Biomedical has sponsored several additional clinical studies. One study in particular, the RESTORE Trial, is investigating whether Sparrow Ascent can improve relapse prevention in adults suffering from opioid use disorder. In 14 patients, who experienced a total of 943.6 hours of skin contact with an active Earpiece, there were no instances of adverse tissue reactions reported.

CONCLUSION

Based on non-clinical testing, it can be concluded that the subject device does not raise concerns of safety or effectiveness compared to the predicate device. The identical indications for use, and similar technological characteristics and performance characteristics for the proposed Sparrow Ascent demonstrate the subject device is substantially equivalent to the predicate device.