August 25, 2025

Spark Biomedical, Inc.
% Erin Gontang, PhD
Senior Consultant
Rqm+
2790 Mosside Blvd, Suite 800
Monroeville, Pennsylvania 15146

Re: K251246
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: April 22, 2025
Received: July 25, 2025

Dear Dr. Gontang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

ROBERT KANG -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251246

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.

510(k) Summary
K251246

DATE PREPARED
August 25, 2025

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 Physical Medicine 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***	***Predicate/Reference***	***Product Code / Reg Number***
K230796	Sparrow Ascent / Spark Biomedical, Inc.	Primary Predicate	PZR / 21 CFR 882.5896
K233166	NET Device / Net Recovery	Reference Device	PZR / 21 CFR 882.5896

Neither the predicate nor the reference device have 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 around the auricle (ear). The device is indicated as an aid in the reduction of opioid withdrawal symptoms in adult patients. The Sparrow Ascent is a battery operated, prescription device that delivers mild electrical stimulation to the nerves 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 (amplitude) 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 is identical to that cleared in K230796, with the exception of a modification to the device Earpiece. While both the subject and predicate devices have an electrode that stimulates the auricular branch of the vagus nerve (ABVN), the predicate device does so via an electrode within the cymba concha, whereas the subject device does so via an electrode on the mastoid. The electrodes provide identical output, thereby providing equivalent stimuli to the ABVN. The change in the Sparrow Ascent Earpiece design does not change the device principle of operation, and there has been no change to the materials used to manufacture the earpiece. Furthermore, although the overall size of the earpiece has been reduced, an assessment of the overall ratios of the patient contacting materials in the revised Sparrow Ascent Earpiece relative to the predicate device earpiece were determined to be equivalent.

Spark Biomedical also evaluated functional magnetic resonance imaging (fMRI) data to show that the spatial distribution of brain activity following mastoid and cymba concha stimulation of

the ABVN was the same. The sham-controlled study looked at 24 healthy adults (mean age: 34.3 ± 11.2 years), and the brain activation maps showing mastoid and cymba concha stimulation were significantly correlated
($r = 0.61$, $p < 0.001$). The results indicated consistent central responses between the two stimulation sites, and the mastoid site demonstrated reliable stimulation-induced brain activation across participants.

The subject device is similar to the reference device (NET Device; cleared in K233166), which uses a similar ABVN stimulation site and has similar outputs to support the intended use of reducing the signs and symptoms associated with opioid withdrawal. The current density (i.e., the output related to nerve activation) is similar between the subject and the reference devices and helps demonstrate equivalent effectiveness. Additionally, power and charge density (i.e., the output related to the impact on the stimulation site) is similar between the subject, the predicate, and the reference devices, and helps demonstrate equivalent safety. This comparison helps demonstrate that the subject device's equivalence to the predicate is supported by the reference.

	Spark Biomedical Sparrow Ascent K251246	**Spark Biomedical Sparrow Ascent K230796**	**Net Recovery NET Device K233166**	**Comparison to Predicate**
	Subject Device	***Primary Predicate***	***Reference Device***	
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 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 NET Device is a transcutaneous alternating current stimulator (tACS) 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.
Stimulation Sites (electrode placement)	Trigeminal & Mastoid	Trigeminal & Cymba Concha	Mastoid	Similar. The subject device now stimulates the ABVN via the mastoid as opposed to the cymba concha. Clinical data shows equivalent brain activation following stimulation at both sites. The reference device also

				stimulates the ABVN via the mastoid. The cleared reference device shares the same IFU and the same electrode position as the subject device.
Product Code / Regulation	PZR / 21 CFR 882.5846	PZR / 21 CFR 882.5846	PZR / 21 CFR 882.5846	Identical.
Patient Population	Adult	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	6.8 @ 500 Ω 25 @ 2K Ω 77 @ 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	14.1 @ 500 Ω 12.4 @ 2K Ω 7.7 @ 10K Ω	Identical.
Maximum Pulse Width (µs)	750	750	750	Identical.
Maximum Frequency (Hz)	150	150	3,000	Identical.
Area of Smallest Electrode (cm^2)	1.181	0.853	2.080	Similar. The observed parameter differences do not affect the substantial equivalence of the subject device to the predicate.
Power Density (rms W/cm^2)	0.002 @ 500 Ω 0.007 @ 2K Ω 0.051 @ 10K Ω	0.003 @ 500 Ω 0.01 @ 2K Ω 0.07 @ 10K Ω	Not Reported as RMS	Similar. The observed parameter differences do not affect the substantial equivalence of the subject device to the predicate.
Max Average Power Density (W/cm^2 @ 4Hz and 750 µs)	Reported as RMS	Reported as RMS	0.57 @ 2K Ω 0.68 @ 10K Ω	Identical.

SUMMARY OF NON-CLINICAL TESTING

In addition to testing performed to support the clearance of K230796 (e.g., biocompatibility), which remains applicable to the subject device, verification testing of the revised Sparrow Ascent Earpiece was conducted. Additionally, extended service life testing was completed for the subject device to verify a service life of 3 years. Non-clinical performance testing verified that, like the predicate, the subject device operates as expected when used as intended, and both meets and satisfies product requirements. As such, it is concluded that the subject device can safely and effectively deliver transcutaneous peripheral nerve stimulation when used as intended.

SUMMARY OF CLINICAL TESTING

To demonstrate similar spatial distribution of brain activity between mastoid and cymba concha stimulation sites, a functional magnetic resonance imaging (fMRI) study was conducted to compare central nervous system activation patterns during stimulation at each site. The fMRI study looked at 24 healthy adults (mean age: 34.3 ± 11.2 years) and was a sham-controlled, crossover study with three stimulation targets: the cymba concha, mastoid, and earlobe. Each subject underwent concurrent transcutaneous auricular vagus nerve stimulation (taVNS) and fMRI during three 8-minute stimulation blocks per site, randomized and counterbalanced, using a 30-second ON/OFF stimulation paradigm. The subject's brain responses were evaluated using general linear modeling (GLM), and functional activation maps were generated and compared across conditions.

The fMRI study showed that both mastoid and cymba concha stimulation elicited overlapping spatial patterns of brain activity. One-sample t-test analyses were performed across the 24 subjects, and activation maps showing mastoid and cymba concha stimulation were significantly correlated ($r = 0.61$, $p < 0.001$), indicating consistent central responses between the two stimulation sites. The findings of the fMRI study support the anatomical and functional equivalence of the mastoid site to the cymba concha for auricular branch of the vagus nerve (ABVN) activation. As such, the modification to the subject device Earpiece constitute a minor modification that does not change the intended use of the device, nor does it introduce different questions of safety or effectiveness.

CONCLUSION

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