May 29, 2024

Net Recovery
℅ John Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K233166
Trade/Device Name: NET Recovery Corp/NET Device
Regulation Number: 21 CFR 882.5896
Regulation Name: Percutaneous nerve stimulator for substance use disorders
Regulatory Class: Class II
Product Code: PZR
Dated: April 25, 2024
Received: April 25, 2024

Dear Dr. Smith:

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.

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 M. Stefani -S

Digitally signed by Robert M. Stefani -S
Date: 2024.05.29 13:20:15 -04'00'

for Pamela Scott, MS
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)*

K233166

Device Name

NET Device

Indications for Use *(Describe)*

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.

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
NET Recovery Corp's NET Device
K233166

Submitter:
Net Recovery Corp
Phone: 856-220-4691
Contact Person: Joe Winston
Date Prepared: 05/24/2024

Name of Device: NET Device

Common or Usual Name: Transcutaneous Alternating Current Stimulator for Opioid Withdrawal

Classification Name: Percutaneous nerve stimulator for substance use disorders

Regulation Number: 21 CFR 882.5896

Regulatory Class: Class II

Product Code: PZR

Predicate Devices

Submission Number	*Device Name / Manufacturer*	*Reference*
K201873	Sparrow Therapy System / Spark Biomedical, Inc.	Primary Predicate
DEN170018	NSS-2 Bridge / Innovative Health Solutions (HIS), Inc.	Reference Device

Device Description

The NET Device is a non-invasive, battery-powered, portable, re-usable, prescription device designed to provide bilateral, transcranial, transcutaneous, alternating current stimulation (tACS) to be used in patients experiencing opioid withdrawal under the supervision of trained clinical personnel. The system is comprised of one component (the NET Device), accessories (patient leads, electrodes, USB cable), and software (the clinician application). NET Devices, patient leads, and USB cables are reusable. No reprocessing, sterilization, maintenance, or recalibration is required. Electrodes are for single patient use only. The NET Device is used in professional healthcare facility environments (e.g., rehab centers and hospitals). If benefit is not established within 60 minutes of use, discontinue use and seek other methods of treatment.

Intended Use / Indications for Use

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.

The indications for use between the NET Device and the predicate device are similar.

Summary of Technological Characteristics

Most individuals with opioid use disorder have significant levels of tolerance and will experience withdrawal on abrupt discontinuation of opioid substances (DSM-5). Electrical stimulation at the auricular region has been shown to reduce COWS (Clinical Opiate Withdrawal Scale).

The NET Device has the same general intended use and similar indications, technological characteristics, and principles of operation as the previously cleared predicate Sparrow Therapy System. Auricular transcutaneous electrical stimulation is the technological principle for both the subject and predicate devices.

The subject and predicate devices are based on the same technological elements:

- Transcutaneous delivery of stimulation.
- Location of electrodes at the auricular region.
- Battery-powered.
- Pre-gelled, self-adhesive, flexible cutaneous, single user, non-sterile, stimulating electrodes.

The following technological differences exist between the subject and predicate devices:

- The predicate device is located at the left auricular region only and the subject device is located at both left and right auricular regions.
- The subject device has a higher instantaneous electrical output.
- The subject device has a higher frequency range.

A table comparing the indications of the subject and predicate device is provided below.

Model Name	**NET Device (Subject Device)**	**Sparrow Therapy System (Primary Predicate)**
Manufacturer	NET Recovery Corp	Spark Biomedical, Inc.
Indications for Use	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.	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.

A table comparing the technological characteristics of subject, predicate, and reference devices is provided below.

Model Name	NET Device (Subject Device)	Sparrow (K201873)	NSS-2 Bridge (DEN 170018)	Remark
MAXIMUM VOLTAGE (V)	6.8 @ 500 Ω 25 @ 2K Ω 77 @ 10K Ω	2.5 @ 500 Ω 10 @ 2K Ω 50 @ 10K Ω	3.2 @ 500 Ω 3.2 @ 2K Ω 3.2 @ 10K Ω	Different[1]
MAXIMUM CURRENT (mA)	14.1 @ 500 Ω 12.4 @ 2K Ω 7.7 @ 10K Ω	5.0 @ 500 Ω 5.0 @ 2K Ω 5.0 @ 10K Ω	6.4 @ 500 Ω 1.6 @ 2K Ω 0.32 @ 10K Ω	Different[1]
MAXIMUM PULSE WIDTH (uS)	750	750	1000	Same as Predicate
Maximum Charge Density (uC/cm2)	6.8 @ 2K Ω 2.77 @ 10K Ω (4Hz, 750uS)		48.91 @ 1K Ω 5.79 @ 10K Ω (10Hz, 1000uS)	Different[1]
Max Avg Current Density (mA/cm2)	0.38 @ 2K Ω 0.18 @ 10K Ω (4Hz, 750uS)			n/a
Max Avg Power Density (mW/cm2)	0.57 @ 2K Ω 0.68 @ 10K Ω (4Hz, 750uS)		264.5 @ 1K Ω 37.1 @ 10K Ω (10Hz, 1000uS)	Different[1]
MAXIMUM FREQUENCY (Hz)	3000	150	1-10	Different[1]
Stimulation Interface	Transcutaneous, left and right	Transcutaneous, left only	Percutaneous	Different[1]

[1]The subject device has substantially similar technological characteristics as compared to the predicate device and reference device, with higher output and frequency ranges, and substantially smaller charge densities and power. The reference device NSS-2 Bridge (DEN170018) has a maximum average power density that is on the order of 100x greater than the subject device, accruing safety benefits to the subject device. Clinical performance data was collected to demonstrate observed parameter differences between the subject device and the predicate device do not affect the substantial equivalence of the subject device to the predicate.

While the delivery methods for stimulation and the corresponding output parameters differ between the devices, these differences do not raise new questions of safety or effectiveness.

The safety questions posed by differences in the range of output and frequency include whether adverse events such as skin burns and skin irritation are comparable. These are the same questions

of safety as posed by the transcutaneous electrical stimulation by the predicate device. Bench testing for electrical safety has been conducted as per IEC 60601-1, Medical Electrical Equipment. Clinical testing in 108 subjects demonstrates that these risks have not increased with respect to the predicate device.

The effectiveness questions posed by differences in the range of output and frequency include performance in reduction in COWS. These are the same questions of effectiveness posed by transcutaneous electrical stimulation by the predicate device. Clinical testing in 108 subjects demonstrates treatment tolerability for the subject device. The subject device demonstrates substantially equivalent COWS reduction response in opioid withdrawal severity relative to the predicate device (primary endpoint in the pivotal trial).

Summary of Non-Clinical Testing

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 10993-5 Biological Evaluation Of Medical Devices — Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10 Biological Evaluation Of Medical Devices — Part 10: Tests For Irritation And Skin Sensitization

Electromagnetic Compatibility and Electrical Safety

The subject device was tested in compliance to:

- **IEC 60601-1** Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- **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.
- **AIM Standard 7351731**, medical electrical equipment and system electromagnetic immunity test for exposure to radio frequency identification readers - an aim standard. (General II ES/EMC))
- **Other Sources of EMC Immunity**: Immunity to specific RF emitters that are known sources of electromagnetic disturbances (This requirement is per FDA Guidance Document – Electromagnetic Compatibility (EMC) of Medical Devices June 6, 2022)

Software Verification

Software verification included system and component level testing of the application and firmware in accordance with the company’s risk management process.

In all instances, the NET Device functioned as intended and observed test results were as expected. This submission demonstrates compliance with the Special Controls per 21 CFR 882.5896.

Summary of Clinical Testing

The prospective, randomized, parallel-group, sham-controlled, superiority study evaluated the safety and effectiveness of the NET Device in reducing opioid withdrawal symptom severity in persons experiencing opioid withdrawal and in treatment for Opioid Use Disorder (OUD) who have expressed a desire to be opioid abstinent without use of medications for opioid use disorder.

The intent-to-treat population included 59.3% male (64/108) and 40.7% female (44/108) participants, aged 18-65, diagnosed with OUD, with an expressed desire to abstain from illicit opioid use without use of medications for treating OUD. Participants were randomly assigned 49.1% to active (53/108) and 50.9% to sham (55/108) study arms. Participants who entered this study were not undergoing treatment by any other means for substance discontinuation. Participants were enrolled at one US site based on 90% power at alpha 0.05 for detecting a 15% reduction in total COWS scores using a two-sided paired t-test.

The study measured a statistically significant clinically meaningful decline in COWS total score from baseline to 1-hour after start of active NET stimulation. The clinically meaningful decline in COWS total score was defined as ≥15% reduction from baseline to 1-hour after start of active NET stimulation. The mean (SD) COWS total score in the active NET group decreased from baseline of 18.1 (4.4) to 1-hour of 7.0 (4.1). This mean decrease of 11.1 (5.2) was statistically significant and exceeded the pre-specified 15% criterion, and 98.1% of the active group had a COWS score reduction of 15% or greater. The mean reduction in COWS score was statistically significantly greater in the active NET group at -11.13 (5.19) than the sham group at -8.75 (6.29). 83.6% of sham participants obtained a 15% reduction in COWS. Of the 53 active participants, 52 completed the study, with one early withdrawal due to headache.

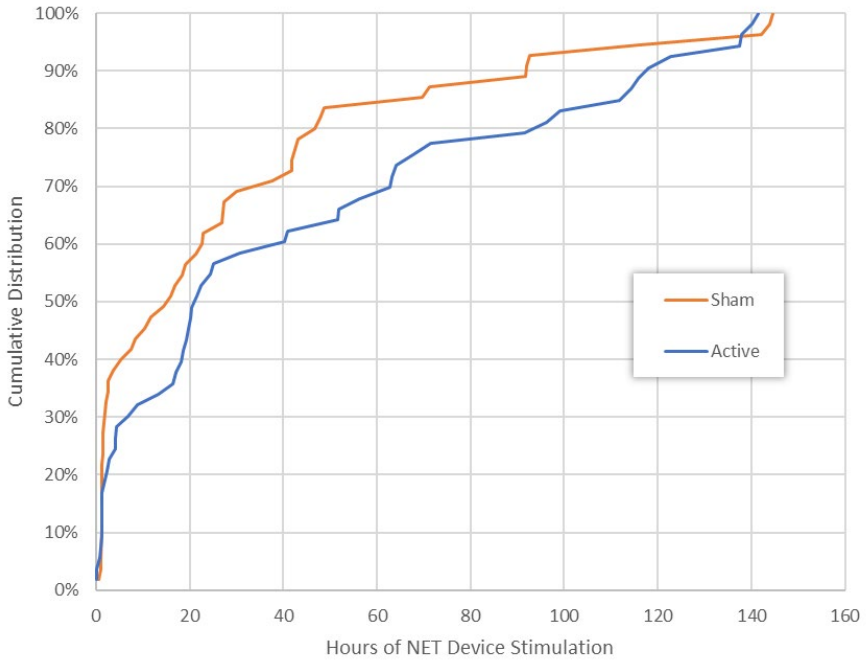
Cohort	Active			Sham			
	Baseline (n, mean, SD)	1 hour (n, mean, SD)	Within-group change % CI	Baseline (n, mean, SD)	1 hour (n, mean, SD)	Within-group change % CI	Between group difference % CI
ITT	53, 18.1, 4.4	52, 7.0, 4.1	-61% ±6%	55, 18.6, 4.0	55, 9.8, 5.4	-46% ±8%	15% ±10%

The following table illustrates the timeline trajectory for device use and data collection from baseline through day 7 (inpatient phase). For each measurement activity, the mean (SD) COWS score for each study arm and the total population were computed. Measurements were taken from all participants receiving stimulation or as a single final measurement following discontinuation.

	Timeline Trajectory for Device Use and Data Collection: COWS mean (SD), n							
	Baseline	**1-Hour**	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**
Active	18.1 (4.4), n=53	7.0 (4.2), n=52	7.9 (6.3), n=47	6.7 (6.0), n=47	4.6 (4.6), n=44	3.5 (3.4), n=40	3.7 (3.9), n=39	3.9 (4.3), n=39
Sham	18.6 (4.0), n=55	9.8 (5.4), n=55	9.6 (7.6), n=50	7.4 (6.3), n=49	4.9 (3.9), n=45	4.3 (3.8), n=41	4.6 (4.0), n=38	3.8 (3.5), n=39
Total	18.4 (4.2), n=108	8.5 (5.0), n=107	8.8 (6.9), n=97	7.1 (6.1), n=96	4.7 (4.2), n=89	3.9 (3.6), n=81	4.2 (4.1), n=77	3.9 (4.1), n=78

The following figure illustrates the cumulative distribution of the percentage of participants in active and sham arms (vertical axis) having received the number of hours of stimulation with the NET Device

(horizontal axis). Treatment was self-administered, with participant control of device output intensity and duration according to perceived benefit. Treatment duration was one-hour, with self-administered extension of active/sham treatment not to exceed 7 days. The experimental design allowed discontinuation after conclusion of patient perceived beneficial effect.



The following table illustrates the cumulative MOUD utilization during the inpatient phase, where such utilization followed cessation of device stimulation.

	Cumulative Inpatient MOUD on Day:						
	1	**2**	**3**	**4**	**5**	**6**	**7**
Active (53)	7 (13%)	12 (23%)	12 (23%)	12 (23%)	11 (21%)	12 (23%)	10 (19%)
Sham (55)	11 (20%)	21 (38%)	22 (40%)	21 (38%)	22 (40%)	22 (40%)	20 (36%)
Total (108)	18 (17%)	33 (31%)	34 (31%)	33 (31%)	33 (31%)	34 (31%)	30 (28%)

As post hoc exploratory observations, duration of stimulation (>1 day) was strongly correlated with 12-week outpatient opioid abstinence without MOUD for the active arm. Active participants with more than 1 day of stimulation were significantly less likely to receive inpatient MOUD immediately following cessation of stimulation (i.e., less likely to need rescue medication to manage symptoms of acute withdrawal immediately following discontinuation of stimulation). The following table illustrates the illicit opioid use during the outpatient phase, as measured by oral fluid drug screen or by timeline follow back interview represented by percent of respondents.

Outpatient Week

	1	2	3	4	5	6	7	8	9	10	11	12
active	6%	13%	11%	3%	8%	8%	10%	6%	3%	6%	9%	3%
sham	0%	9%	11%	11%	3%	7%	7%	11%	11%	10%	12%	14%

The population had very high rates of recent fentanyl exposure at 71.3% (77/108) based on urine drug testing at screening. Fentanyl exposure was evenly distributed across active/sham groups and across sex. Participants with fentanyl-positive urine drug screen (UDS) at screening had mean COWS withdrawal scores that were numerically, but not significantly, higher at baseline and at 1-hr than participants with fentanyl-negative UDS; there was no difference in COWS change scores from baseline to 1-hr for fentanyl-positive vs. fentanyl-negative UDS groups.

The population had moderately high rates of exposure to psychostimulants tested by UDS at screening (methamphetamine, amphetamine, cocaine, MDMA) at 50.0% (54/108) but specifically methamphetamine at 42.6% (46/108). Stimulant exposure was evenly distributed across active/sham groups and was more prevalent among females at 59.1% than males at 43.8%. Presenting stimulant-positive at screening had no discernible effects on COWS withdrawal scores.

Device treatment perception ("sham credibility") was assessed at 1-hr post-stimulation, and the blind was not maintained (two-tail p=0.096). Although not all participants knew their device assignment, more participants who were assigned to active NET perceived it to be active stimulation, whereas participants assigned to the sham device were unsure.

Acceptability of device use was assessed, with 51.9% of the active group being highly satisfied and 80.8% being highly willing to use the device at 1-hour after start of stimulation. In anonymous assessments, 87% of treatment staff members (13/15) reported they were very likely or extremely likely to favor offering the NET treatment as part of their standard clinical protocol.

There were no device-related adverse events (ADEs, SADEs, or UADEs). The participant population and study site medical staff were proactively interviewed with structured and open questions to identify and document adverse events of special interest (AESI). Interviews were conducted daily during the first seven days and then weekly during inpatient and outpatient phases.

The clinical performance as documented in the pivotal clinical study demonstrates the safety and effectiveness of the NET Device and supports substantial equivalence to the predicate device.

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 Sparrow Therapy System, was granted FDA clearance (K201873). In the publication, the average age at enrolment was 35.5 years and the proportion of male participants was 65%. In the subject device study, the average age at enrolment was 34.1 years and the proportion of male participants was 59%. In the predicate study, the average baseline COWS score across all enrolled participants was 15.6 and the average baseline COWS score in the subject device study was 18.1. These values both correspond to moderate withdrawal

symptoms. Also, similar to the predicate study, most participants fell into the moderate withdrawal category (95% in the predicate device study compared to 91% in the subject device study).

For the predicate device, the mean COWS score decreased from an average of 15.6 points 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 subject device, the mean COWS score decreased from an average of 18.1 points at baseline to an average of 7.0 points at 60 minutes, demonstrating a mean reduction in the COWS score of 61.3% at 60 minutes (n=52). The subject device demonstrated greater reduction in the COWS score at 60 minutes after treatment compared to the predicate device. The risk profiles for the subject and predicate devices are comparable, with both using transcutaneous nerve stimulation delivered through non-invasive earpieces that does not puncture the skin.

Based on this benefit-risk assessment, it was determined that the NET Device could be found substantially equivalent to the predicate device for the indication for use as a transcutaneous alternating current stimulator (tACS) that is intended to be used in patients experiencing opioid withdrawal, aged 18 and older, diagnosed with opioid use disorder, who have a Clinical Opiate Withdrawal Scale (COWS) score of moderate, for opioid withdrawal symptoms, in conjunction with standard symptomatic medications and other therapies for opioid withdrawal symptoms under the supervision of trained clinical personnel.

Conclusions

The NET Device is as safe and effective as the Sparrow Therapy System. The NET Device has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the NET Device and its predicate device raise no new issues of safety or effectiveness. Clinical and non-clinical performance data demonstrate that the NET Device is as safe and effective as the Sparrow Therapy System. Thus, the NET Device is substantially equivalent to the predicate.