June 20, 2024

Curonix
% Danielle Besal
Principal Consultant
MRC Global, LLC
9085 E. Mineral Circle, Suite 110
Centennial, Colorado 80112

Re: K233162
Trade/Device Name: Freedom Peripheral Nerve Stimulator (PNS) System
Regulation Number: 21 CFR 882.5870
Regulation Name: Implanted Peripheral Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZF
Dated: May 17, 2024
Received: May 17, 2024

Dear Danielle Besal:

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,

Amber T. Ballard -S

Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation 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)*
K233162

Device Name
Freedom Peripheral Nerve Stimulator (PNS) System

Indications for Use *(Describe)*
The Freedom Peripheral Nerve Stimulator (PNS) System is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The Freedom Trial Lead Kit is only to be used in conjunction with the Freedom Neurostimulator Kit. The trial devices are solely used for a trial stimulation period (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.

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.**

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**510(k) Summary**

*Freedom Peripheral Nerve Stimulator (PNS) System*

*K233162*

*June 20, 2024*


**Company:** Curonix
1310 Park Central Blvd S.
Pompano Beach FL 33064

**Primary Contact:** Danielle Besal
Principal Consultant | MRC Global
901.827.8670
Danielle.Besal@askmrcglobal.com

**Company Contact:** Hailey Rooney
Vice President, Quality and Regulatory
800.965.5134
Hailey.Rooney@curonix.com


**Trade Name:** Freedom Peripheral Nerve Stimulator (PNS) System
**Common Name:** Implanted peripheral nerve stimulator
**Classification:** Class II
**Regulation Number:** 21 CFR 882.5870 Implanted peripheral nerve stimulator for pain relief
**Product Code:** GZF
**Predicate Devices:** K171366 StimQ Peripheral Nerve Stimulator System

**Device Description:**

The Freedom PNS System uses HF-EMC (High Frequency Electromagnetic Coupling) neurostimulation technology to provide therapeutic relief for chronic, intractable pain of peripheral nerve origin. The Freedom PNS System is comprised of a two-component implantable neurostimulator, an externally-worn transmitter, and WaveCrest software used to set patient-specific stimulation programs. The system's mechanism of action relies on programmable pulsed electrical current to create an energy field that acts on the targeted peripheral nerve to inhibit the transmission of pain signals to the brain. The two-component neurostimulator, comprised of an electrode array and a separate receiver, are surgically connected and anchored within two separate incisions, including creation of a subcutaneous pocket. The stimulation program is adjusted as needed to provide pain relief for the patient. The purpose of this submission is to modify the indications for use for the existing system (K171366) to include craniofacial applications.

The Freedom PNS System is a single-use, prescription-only system, to be implanted by an appropriate clinician, such as a neurosurgeon, interventional pain physician, craniofacial surgeon or orthopedic surgeon. The system components are described in **Table 1**.

**Table 1. System Components**

| Component | Description |
|---|---|
| **Neurostimulator – Permanent Implant (two components)** | The Neurostimulator consists of two permanently implanted components that are connected during the surgical procedure, a 4- or 8-Electrode Array and a separate Receiver. The Electrode Array is placed next to the target peripheral nerve through the first incision. Through a second incision, the Receiver is then connected to the electrode array and anchored within a subcutaneous pocket. |

| Component | Description |
|---|---|
| **Electrode Array**<br>**(First Implanted Component)** | The Electrode Array is comprised of a polyurethane casing, flexible circuit board, ASIC chip, and 4 or 8 electrodes (platinum iridium alloy, 90:10 w%). The Electrode Array contains a port designed to connect with the separate Receiver component. |
| **Receiver**<br>**(Second Implanted Component)** | The Receiver is an HF-EMC conductor that receives wireless power and data signals from the External Transmitter Assembly. The Receiver device consists of a PEEK-coated copper core that is precisely tuned to the HF-EMC frequency. The Receiver connects to the Electrode Array connection port to form the Neurostimulator. |
| **Neurostimulator – Trial Implant** | Trial Neurostimulators (Leads) are available for trial stimulation (no longer than 30 days) to determine efficacy for an individual patient before recommendation for a permanent (long-term) device. Following the trial period, the Trial Lead must be explanted. If determined that permanent implantation would be appropriate for the patient, the surgeon then implants the permanent Neurostimulator(s). |
| **Transmitter Assembly** | The Transmitter Assembly utilizes HF-EMC to provide power and data to the implanted Receiver and transmits stimulation parameter settings embedded on the carrier frequency, which includes the waveform pulse shape, pulse rate, pulse width, and amplitude. A single Transmitter Assembly may power multiple implanted Neurostimulators. The Transmitter Assembly consists of a Transmitter and an Antenna:<br>• The Transmitter houses the following components:<br>  ○ Microwave field stimulator (MFS) - A printed circuit board (PCB) that generates 915 MHz RF power with embedded waveform parameter settings and circuitry to enable changing parameter settings as needed by the user.<br>  ○ Switch membrane (Buttons) - Elastomeric silicon rubber pad that corresponds to switches on the MFS that allows the user to turn the device on/off or increase or decrease power amplitude as well as interpret device power status (On, Off, Charging, Transmitting, and Bluetooth® Connection).<br>  ○ Battery assembly – a rechargeable battery and wire assembly for MFS power delivery.<br>• Transmitting (Tx) Antenna – An antenna and cable assembly that is attached to the Transmitter Assembly and used to transmit energy to the implanted Receiver. |
| **Accessories** | • Steering Stylet – A stainless steel stylet with a polypropylene handle that is inserted into the open central lumen of the Electrode Array to provide rigidity during implantation; available in curved and straight configurations.<br>• Guidewire – A stainless steel, rigid, solid core guidewire that may be used to create a hollow pathway for the Electrode Array through the tissue.<br>• Introducer Assembly – a 15-gauge stainless steel dilator and yellow Hytrel introducer assembly that acts as a conduit for passage of the electrode array next to the targeted peripheral nerve.<br>• Charging Accessory – An off-the-shelf battery charger that uses a power adapter and USB cable to recharge the lithium-ion battery of the Transmitter Assembly.<br>• Wearable Accessories – A wearable, elastic neoprene sleeve worn to house the Transmitter Assembly; available in vertical/horizontal configurations in various sizes and torso configuration in various sizes, with potential extender available. configuration is available to hold the antenna in place when using the subject system for craniofacial applications.<br>• Transmitter Cover Accessory – A removable cover that snaps onto the Transmitter Assembly providing to reduce the likelihood inadvertent pressing of the Transmitter buttons. |

| Component | Description |
|---|---|
| **WaveCrest Software** | An iPad application, WaveCrest™, is used by trained company representatives to program the Transmitter Assembly. |

**Indications for Use**:
The Freedom Peripheral Nerve Stimulator (PNS) System is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The Freedom Trial Lead Kit is only to be used in conjunction with the Freedom Neurostimulator Kit. The trial devices are solely used for a trial stimulation period (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.

**Substantial Equivalence:**
The Freedom PNS System is substantially equivalent to the predicate device (K171366). The subject and predicate devices are similar in intended use, materials, and technological characteristics. The difference in the subject device's indication for use versus the predicate is supported by clinical data demonstrating the safety and effectiveness of the subject system in craniofacial applications. A detailed comparison is provided in **Table 2**.

**Table 2. Substantial Equivalence Comparison**

| **Device Type** | **SUBJECT DEVICE** | **PREDICATE DEVICE** | **Substantial Equivalence Discussion** |
|---|---|---|---|
| **Name** | **Freedom PNS System** | **StimQ PNS System** | |
| **510(k) Clearance** | TBD | K171366 | |
| **Prescription Use/OTC** | Rx Only | Rx Only | Identical |
| **Product Code** | GZF | GZF | Identical |
| **Indications for Use** | The Freedom Peripheral Nerve Stimulator (PNS) System is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The Freedom Trial Lead Kit is only to be used in conjunction with the Freedom Neurostimulator Kit. The trial devices are solely used for a trial stimulation period (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device. | The StimQ Peripheral Nerve Stimulator (PNS) System is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The StimQ PNS System is not intended to treat pain in the craniofacial region. The StimQ Trial Lead Kit is only used in conjunction with the StimQ Stimulator Receiver Kit. The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device. | Substantially equivalent. A clinical study of the subject device implanted in the craniofacial region showed the trial met its primary effectiveness, primary safety, and secondary endpoints; thus, demonstrating its acceptability for use treating peripheral nerves in the craniofacial region. |
| **Mode of Action** | RF wireless transmission of energy to produce stimulation at Neurostimulator electrodes. Transmitter Assembly sends a pulsed RF signal on a carrier frequency of 915MHz to the Receiver. | RF wireless transmission of energy to produce stimulation at Stimulator electrodes. SWAG sends a pulsed RF signal on a carrier frequency of 915MHz to the Stimulator. | Identical |
| **Environment of Use** | Hospital, Home | Hospital, Home | Identical |
| **Intended Clinician** | Orthopedic, Neurosurgeon, Pain Physician, Anesthesiologist, Craniofacial Surgeon | Orthopedic, Neurosurgeon, Anesthesiologist | Additional intended clinician population per expanded indication for use. |
| **Device Type** | **SUBJECT DEVICE** | **PREDICATE DEVICE** | |

| Name | Freedom PNS System | StimQ PNS System | Substantial Equivalence Discussion |
|---|---|---|---|
| **510(k) Clearance** | TBD | K171366 | |
| **Intended User** | Layperson | Layperson | Identical |
| **Stimulator Body Material** | Polyurethane 2363-55D | Polyurethane 2363-55D | Identical |
| **Electrode Material** | Platinum-iridium 90:10 | Platinum-iridium 90:10 | Identical |
| **Cable Features** | Multi-lumen Tube | Multi-lumen Tube | Identical |
| **Stimulator Length** | 45 centimeters | 45 centimeters | Identical |
| **Diameter** | 1.35 millimeters | 1.35 millimeters | Identical |
| **Electrode Array Length** | 24 millimeters<br>52 millimeters | 24 millimeters<br>52 millimeters | Identical |
| **No. of Electrodes** | 4 or 8 | 4 or 8 | Identical |
| **Electrode Length** | 3.0 millimeters | 3.0 millimeters | Identical |
| **Electrode Spacing** | 4.0 millimeters | 4.0 millimeters | Identical |
| **Electrode Surface Area** | 12.72 $mm^2$ | 12.72 $mm^2$ | Identical |
| **Method of Introduction** | Percutaneous | Percutaneous | Identical |
| **Tissue Contact** | Yes | Yes | Identical |
| **Sterilization** | Ethylene Oxide (EO) | Ethylene Oxide (EO) | Identical |
| **Labeling** | Labeled as Sterile, Single Use, Prescription Device | Labeled as Sterile, Single Use, Prescription Device | Identical |
| **Package** | Backer card and two sterile pouches | Backer card and two sterile pouches | Identical |
| **Pulse Frequency** | 5 to 1500 Hertz | 5 to 1500 Hertz | Identical |
| **Pulse Width** | 50 to 500 microseconds | 50 to 500 microseconds | Identical |
| **Current/Voltage Regulated** | Current | Current | Identical |
| **Output Voltage (300 Ω)** | 0 to 4.1 V | 0 to 4.1 V | Identical |
| **Output Voltage (500 Ω)** | 0 to 6.4 V | 0 to 6.4 V | Identical |
| **Output Voltage (800 Ω)** | 0 to 7.5 V | 0 to 7.5 V | Identical |
| **Output Current (300 Ω)** | 0 to 13.5 mA | 0 to 13.5 mA | Identical |
| **Output Current (500 Ω)** | 0 to 12.8 mA | 0 to 12.8 mA | Identical |
| **Output Current (800 Ω)** | 0 to 9.4 mA | 0 to 9.4 mA | Identical |
| **Waveform** | Charge Balanced (delayed) Biphasic asymmetrical | Charge Balanced (delayed) Biphasic asymmetrical | Identical |
| **Polarity** | Programmable (Anode, Cathode, or Off) | Programmable (Anode, Cathode, or Off) | Identical |
| **Pulse Shape** | Decaying Exponential | Decaying Exponential | Identical |
| **Avg. Current Density (300 Ω)** | 105.0 $mA/cm^2$ | 105.0 $mA/cm^2$ | Identical |
| **Avg. Current Density (500 Ω)** | 95.1 $mA/cm^2$ | 95.1 $mA/cm^2$ | Identical |
| **Avg. Current Density (800 Ω)** | 69.0 $mA/cm^2$ | 69.0 $mA/cm^2$ | Identical |
| **Max. Phase Charge* (300 Ω)** | 6.8 µC/pulse | 6.8 µC/pulse | Identical |
| **Max. Phase Charge* (500 Ω)** | 6.4 µC/pulse | 6.4 µC/pulse | Identical |
| **Max. Phase Charge* (800 Ω)** | 4.7 µC/pulse | 4.7 µC/pulse | Identical |
| **Max. Charge Density* (300 Ω)** | 53.1 $µC/cm^2$ | 53.1 $µC/cm^2$ | Identical |
| **Max. Charge Density* (500 Ω)** | 50.3 $µC/cm^2$ | 50.3 $µC/cm^2$ | Identical |
| **Max. Charge Density* (800 Ω)** | 36.9 $µC/cm^2$ | 36.9 $µC/cm^2$ | Identical |
| **Max. Current Density* (300 Ω)** | 106.1 $mA/cm^2$ | 106.1 $mA/cm^2$ | Identical |
| **Max. Current Density* (500 Ω)** | 100.6 $mA/cm^2$ | 100.6 $mA/cm^2$ | Identical |
| **Max. Current Density* (800 Ω)** | 73.9 $mA/cm^2$ | 73.9 $mA/cm^2$ | Identical |
| **Net Charge** | 0 µC | 0 µC | Identical |
| **Avg. Phase Power (300 Ω)** | 0.053 W/phase | 0.053 W/phase | Identical |
| **Avg. Phase Power (500 Ω)** | 0.073 W/phase | 0.073 W/phase | Identical |
| **Avg. Phase Power (800 Ω)** | 0.062 W/phase | 0.062 W/phase | Identical |
| **Avg. Phase Power Density (300 Ω)** | 0.42 $W/cm^2$/phase | 0.42 $W/cm^2$/phase | Identical |
| **Avg. Phase Power Density (500 Ω)** | 0.58 $W/cm^2$/phase | 0.58 $W/cm^2$/phase | Identical |
| **Avg. Phase Power Density (800 Ω)** | 0.48 $W/cm^2$/phase | 0.48 $W/cm^2$/phase | Identical |
| **Pulse Delivery Mode** | Continuous | Continuous | Identical |
| **ON/OFF Times** | No Cycling | No Cycling | Identical |
| **Current Path Options** | Bipolar | Bipolar | Identical |

| Device Type | SUBJECT DEVICE | PREDICATE DEVICE | Substantial Equivalence Discussion |
|---|---|---|---|
| **Name** | **Freedom PNS System** | **StimQ PNS System** | |
| **510(k) Clearance** | TBD | K171366 | |
| **Power Delivery** | External Transmitter Assembly delivers power to implanted Receiver | Embedded receiver and coupled receiver in lumen of Stimulator body | Identical |
| **Transmit Frequency** | 915 MHz | 915 MHz | Identical |
| **Single-Use** | Yes | Yes | Identical |
| **Shelf Life** | 2 years | 2 years | Identical |
| **Complies with ISO 10993-1** | Yes | Yes | Identical |
| **Safety Testing Passed** | Yes, no new safety testing was required | Yes | Identical |
| **MR Conditional** | Yes, FR4A/STQ4 MR Conditional | Yes, FR4A/STQ4 MR Conditional | Identical |
| **Accessories** | Receiver (Spare), Introducer Assembly, Needle, Stylet(s), Wearables | Receiver/RF Stylet, Stylet, Introducer Assembly, Guidewire | Identical |
| **Charger** | USB Charger | USB Charger | Identical |
| **Transmitter assembly** | Transmitter and Antenna | Aluminum transmitter and separate, connected Antenna | Identical |
| **iPad Application** | WaveCrest™ | WaveCrest™ | Substantially equivalent; minor software changes versus predicate. No new questions of safety or effectiveness were introduced and the changes have been verified and validated. |

**Non-Clinical Performance Testing:**
No modifications were made to the components of K171366 (Freedom-8A/4A Stimulators, Receiver, Transmitter Assembly, WaveCrest software, Battery Charger, Sterilization, Kitting Options) in support of the device safety and performance of this submission. The Freedom PNS System testing is leveraged from prior cleared premarket notifications where components were tested to verify that the performance meets the system design requirements as well as all applicable voluntary standards. The Freedom PNS System complies with all design requirements and applicable voluntary standards.

**Clinical Performance Testing:**
A multi-center randomized clinical trial was conducted on the subject system and demonstrated the subject system met both its primary safety and effectiveness endpoints. Sixty patients were implanted with the Freedom® PNS system in the craniofacial region using an identical minimally invasive surgical technique. At time of surgery, all 60 patients received an External Transmitter for a period of 7 days to confirm the effectiveness of device. During the 7-day activated permanent therapy confirmation period visit, therapy effectiveness was confirmed (at least 50% pain relief) in 56 of the 58 patients that completed the confirmation visit. Those 56 responding patients were randomized during the 7-day confirmation period visit to either an Active (Treatment group) or Deactivated group (Control group). Twenty-eight patients were randomized to the Treatment/Active group and kept their External Transmitter. Twenty-eight patients were randomized to the Control/Deactivated group and their External Transmitters were taken away. Subjects then began the therapy to which they were randomized for evaluation of the primary endpoints at 3 months.

Results showed the continued treatment with the subject device is superior to the deactivated control device in the proportion of patients with significant (at least 50%) pain relief at 3 months compared to baseline and, thus, the primary effectiveness endpoint was met. The primary safety endpoint for the study was also met as treatment with the subject device was shown to be safe, passing the safety hypothesis test by demonstrating the proportion of patients with serious adverse events by 3 months

was less than 30%. None of the 60 subjects who had implanted devices (Treatment or Control groups) had serious adverse events.

The results from the clinical study demonstrated that the subject system provided superior pain relief compared to the control deactivated device for stimulation of craniofacial peripheral nerves and demonstrated the system is safe when used with peripheral nerves in the craniofacial region.

**Conclusion:**

The clinical study results are adequate to support the expansion of the indications for use and, thus, the Freedom PNS System is considered substantially equivalent to the predicate StimQ PNS System (K171366).