August 15, 2025

N & C Holdings, LLC
% Tom Renner
Quality, Efficiency and Regulatory Affairs Consultant
Vision28
915 SW Rimrock Way
Suite 201-402
Redmond, Oregon 97756

Re: K252236
Trade/Device Name: CP Relief Wand Rx - TENS/NMES
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZJ, IPF
Dated: March 17, 2025
Received: July 17, 2025

Dear Tom Renner:

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,

Amber T. Ballard -S

Amber Ballard, PhD
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)*
K252236

Device Name
CP Relief Wand Rx - TENS/NMES

Indications for Use *(Describe)*
As a TENS device, the CP Relief Wand Rx - TENS/NM ES is intended for use as an adjunctive therapy for pain management for medical purposes such as symptomatic relief of chronic intractable pain and relief of acute post surgical and post-traumatic pain.

As an EMS device, the CP Relief Wand Rx - TENS/NM ES is intended for use for relaxation of muscle spasm, increasing local blood circulation, muscle re-education, prevention or retardation of disuse atrophy, prevention of venous thrombosis of the calf muscles immediately after surgery, and maintaining on increasing range of motion.

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

I. SUBMITTER

N & C Holdings, LLC

1709 Honey Creek Rd.

Jefferson City MO 65101

Phone: 573-496-3213

Contact Person: Mr. Norm Schroeder

Date Prepared: August 15, 2025

II. DEVICE

Name of Device: CP Relief Wand Rx - TENS/NMES

Common or Usual Name: Transcutaneous electrical nerve stimulator for pain relief

Classification Name: Stimulator, Nerve, Transcutaneous, For Pain Relief (21 CFR 882.5890)

Regulatory Class: II

Product Code: GZJ, IPF

III. PREDICATE DEVICES

CP Relief Wand ® Model CP-1000, K133779

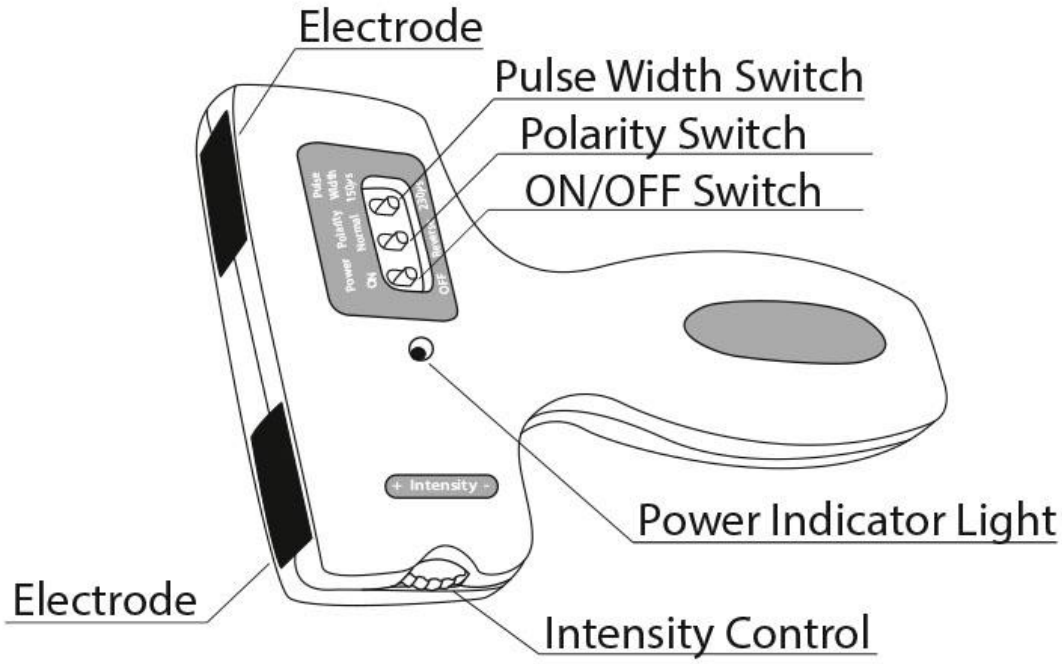
Unipro (K-UNIPRO-US), K232441

IV. DEVICE DESCRIPTION

The CP Relief Wand Rx - TENS/NMES® (“Wand”) is a multitherapy medical device that combines the treatment capabilities of TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation).

The CP Relief Wand Rx - TENS/NMES is portable with self-contained electrodes. The device is powered by a standard non-rechargeable 9-volt alkaline battery. A charger is not used due to the low current drain and long battery life of the low power circuitry.

In operation, the electrode end of the CP Relief Wand Rx - TENS/NMES is positioned to touch the skin. The electrical pulses travel from one electrode, through the skin, through the underlying tissue, and back through the skin to the other electrode. Controls on the unit are provided for power, intensity, pulse width, and pulse polarity.



Intensity Control: The Intensity Control is a thumb dial located on the side for easy access during treatment. This control provides continuous adjustment and control of the amplitude of the pulsating electrical current during treatment. This dial is labeled 0-8 and corresponds to the output setting.

On-Off Switch: This is the main power switch.

Pulse Width Switch: The Pulse Width Switch selects either 150 microsecond pulse width (low) or 230 microsecond (μS) pulse width (high).

Polarity Switch: The Polarity Switch allows selecting the polarity of the electrodes.

Each Model CP Relief Wand Rx - TENS/NMES includes:

1. CP Relief Wand Rx - TENS/NMES device
2. One tube of Spectra 360 Electrode Gel (K971437)
3. One Duracell Alkaline 9 V battery
4. User Manual
5. Quick Start Guide
6. Zip Carrying Case

V. INDICATIONS FOR USE

As a TENS device, the CP Relief Wand Rx - TENS/NMES is intended for use as an adjunctive therapy for pain management for medical purposes such as symptomatic relief of chronic intractable pain and relief of acute post surgical and post-traumatic pain.

As an EMS device, the CP Relief Wand Rx - TENS/NMES is intended for use for relaxation of muscle spasm, increasing local blood circulation, muscle re-education, prevention or retardation of disuse atrophy, prevention of venous thrombosis of the calf muscles immediately after surgery, and maintaining on increasing range of motion.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The proposed “CP Relief Wand Rx - TENS/NMES” is compared to the predicate "CP Relief Wand ® Model CP-1000" (K133779) and to a second predicate device “Unipro (K-UNIPRO-US)” from TensCare Ltd (K232441).

Regulatory Parameters

Comparison	CP Relief Wand Rx - TENS/NMES	"CP Relief Wand ® Model CP-1000" (K133779) PREDICATE	Unipro (K-UNIPRO-US) (K232441) SECOND PREDICATE
Indications for use	As a TENS device, the CP Relief Wand Rx - TENS/NMES is intended for use as an adjunctive	The CP Relief Wand® CP-1000 is a TENS Device and is intended for use as an adjunctive therapy for pain	TENS stands for Transcutaneous Electrical Nerve Stimulation. Unipro TENS is used to provide

	therapy for pain management for medical purposes such as symptomatic relief of chronic intractable pain and relief of acute post surgical and post-traumatic pain. As an EMS device, the CP Relief Wand Rx - TENS/NMES is intended for use for relaxation of muscle spasm, increasing local blood circulation, muscle re-education, prevention or retardation of disuse atrophy, prevention of venous thrombosis of the calf muscles immediately after surgery, and maintaining on increasing range of motion.	management for medical purposes such as symptomatic relief of chronic intractable pain and relief of acute post-surgical and post-traumatic pain.	symptomatic pain relief for chronic, acute or post-operative pain. EMS stands for Electrical Neuromuscular Stimulation. Unipro EMS is indicated for: • Relaxation of muscle spasm • Increasing local blood circulation and muscle re-education • Prevention or retardation of disuse atrophy • Prevention of venous thrombosis of the calf muscles immediately after surgery • Maintaining on increasing range of motion MIC stands for Microcurrent Stimulation. Unipro MIC is used to provide sumptomatic pain relief for chronic intractable pain, post traumatic pain or post surgical pain. IFT stands for lnterferntial Stimulation. Unipro IFT is indicated for symptomatic relief ofchronic intractable pain.
Common or usual	Transcutaneous Electrical Nerve	Transcutaneous Electrical Nerve	Transcutaneous Electrical Nerve

name	Stimulator For Pain Relief Powered Muscle Stimulator	Stimulator For Pain Relief	Stimulator For Pain Relief Powered Muscle Stimulator
Regulatory Class	Class II	Class II	Class II
Regulation number and product code	882.5890 - Transcutaneous electrical nerve stimulator for pain relief GZJ, IPF	882.5890 - Transcutaneous electrical nerve stimulator for pain relief GZJ	882.5890 - Transcutaneous electrical nerve stimulator for pain relief GZJ, IPF, LIH

The proposed "CP Relief Wand Rx - TENS/NMES" device, predicate device, and second predicate device are the same in the following regulatory parameters:

- Primary regulation number, common name, and product code
- Regulatory class

With regards to secondary product code, the IPF product code is an expansion from the predicate device, but match the second predicate device. This expansion is the subject of this pre-market filing.

With regards to indications for use, the TENS indication (first sentence) of the proposed "CP Relief Wand Rx - TENS/NMES" device is substantially equivalent to the originally-cleared (K133779) indication, except that it has been modified to differentiate between TENS and EMS claims.

The EMS indication (second sentence) of the proposed "CP Relief Wand Rx - TENS/NMES" device is an expansion of indications from the predicate device. This expanded indication is the subject of this pre-market filing. The EMS indication of the proposed "CP Relief Wand Rx - TENS/NMES" device is substantially equivalent to the EMS indication of the second predicate device.

The second predicate device has additional MIC and IFT indications that are not relevant to the proposed "CP Relief Wand Rx - TENS/NMES" device.

The proposed "CP Relief Wand Rx - TENS/NMES" therefore is modification from the predicate device, but in a manner that conforms to the profile of the second predicate device.

Specifications

Comparison	CP Relief Wand Rx - TENS/NMES	"CP Relief Wand ® Model CP-1000" (K133779) PREDICATE	Unipro (K-UNIPRO-US) (K232441) SECOND PREDICATE
Portable?	Yes	not publicly available	Yes
Housing material	ABS 433	not publicly available	ABS 757
Dimensions (in)	3.9 x 6.0 x 0.9	not publicly available	4.9 x 2.4 x 1.2
Weight (oz)	3.4 oz	not publicly available	4.5 oz
Electroconductive media	Spectra 360 Electrode Gel (K97143)	not publicly available	Self-adhesive gel electrodes
Power Source	9 V alkaline battery	not publicly available	3.7V 1500mAh Lithium-ion battery (rechargeable)
Method of Line Current Isolation	n/a	n/a	Sequential isolation / transformer isolation
Avg. DC current w/no pulses applied (µA)	<0.2 µA	not publicly available	0 µA
Number of output modes	1	not publicly available	4
Number of output channels	1	not publicly available	2
Regulated current or regulated voltage	Voltage	not publicly available	Current and Voltage
Software/Firmware/ Microprocessor Control?	No	not publicly available	Yes
Automatic No-Load Trip?	No	not publicly available	Yes
Automatic Overload Trip?	No	not publicly available	No
Automatic Shut Off?	No	not publicly available	Yes
User Override Control?	No	not publicly available	Yes
On/Off Indicator?	Yes	not publicly available	Yes
Low battery Status?	No	not publicly available	Yes
Voltage/current level Status?	No	not publicly available	Yes

Treatment Timer?	No	not publicly available	Yes
Treatment Time	Continuous	not publicly available	5 - 90 minute preset or Continuous
Waveform	TENS/EMS*: Biphasic rectangular	not publicly available	TENS/EMS: Biphasic rectangular
Maximum Output Voltage (500 Ohms)	TENS/EMS: 42.3 V	not publicly available	TENS/EMS: 54 V
Maximum Output Voltage (2K ohms)	TENS/EMS: 81.5 V	not publicly available	TENS/EMS: 114 V
Maximum Output Voltage (10K ohms)	TENS/EMS: 102.7 V	not publicly available	TENS/EMS: 116 V
Maximum Output Current (500 Ohms)	TENS/EMS: 84.6 mA	not publicly available	TENS/EMS: 108 mA (200µs) TENS/EMS: 80 mA (400µs)
Maximum Output Current (2K Ohms)	TENS/EMS: 40.75 mA	not publicly available	TENS/EMS: 57 mA
Maximum Output Current (10K Ohms)	TENS/EMS: 10.3 mA	not publicly available	TENS/EMS: 11.6 mA
Pulse Width (µs)	TENS/EMS: 150 or 230 µs selectable	not publicly available	TENS: 50-300 µs EMS: 100-400 µs
Frequency (Hz)	TENS/EMS: 40 Hz fixed	not publicly available	TENS: 2-150Hz EMS: 10-120Hz
Net Charge (µC per pulse at 500 Ohms)	TENS/EMS: 19.3 µC	not publicly available	0.3 µC
Maximum Phase Charge (µC at 500 Ohms)	TENS/EMS: 19.55 µC	not publicly available	TENS/EMS: 22.76 µC
Maximum Current Density (mA/cm^2)	TENS/EMS: 1.86 mA/sq. cm. (rms)	not publicly available	TENS/ EMS: 0.8 mA/cm2
Maximum Power Density (W/cm^2)	TENS/EMS: 0.0076 W/cm2	not publicly available	TENS/EMS: 0.0076 W/cm2

The proposed “CP Relief Wand Rx - TENS/NMES” device is technologically identical to the K133779 primary predicate device. The purpose of this submission was to expand the

indications of use to include NMES and change the electroconductive media to a gel.

The proposed “CP Relief Wand Rx - TENS/NMES” device and the second predicate device are substantially equivalent in the following specifications:

- Portability
- Housing material
- Dimensions
- Weight
- Use of conductive gel
- Battery-powered
- Ability to support continuous treatment
- Waveform shape
- Maximum output voltage
- Maximum output current
- Pulse width
- Frequency
- Net Charge
- Maximum Phase Charge
- Maximum power density

The proposed “CP Relief Wand Rx - TENS/NMES” device and the **second predicate** device differ in the following specifications:

- The second predicate device is rechargeable, but the proposed device is not.
- The second predicate device has a variety of additional convenience features relating to display, number of output modes, automatic shutoff, preset treatment timer, status indicators, and selectable pulse widths and frequencies.
- The second predicate device has a lower reported maximum current density (mA/cm^2). However, the maximum power density (W/cm^2) of the proposed device and the second predicate device are identical.
- The second predicate has a lower measured Net Charge (µC per pulse at 500 Ohms) than the proposed device, likely due to its support for higher stimulation frequencies. Like both predicates, the proposed device has a transformer isolated output.

VII. PERFORMANCE DATA

The following performance testing was leveraged from the K133779 primary predicate device:

- IEC60601-1 Edition 2:1988 (A1:1991 + A2:1995) Medical Electrical Equipment; Part 1: General Requirements for Safety and Essential Performance

- IEC60601-1-2:2007 Third Edition, Medical electrical equipment – Section 1.2 Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC60601-2-10 (1987) and Amendment 1 (2001) Medical Electrical Equipment – Part 2-10: Particular requirement for the basic safety and essential performance of nerve and muscle stimulators

VIII. CONCLUSIONS

Based upon comparisons of regulatory parameters and specifications, the proposed “CP Relief Wand Rx - TENS/NMES” device is substantially equivalent to the predicate "CP Relief Wand ® Model CP-1000" (K133779).

Where the proposed “CP Relief Wand Rx - TENS/NMES” device has expanded indications for use to include EMS, the relevant features, including especially waveform attributes, are substantially equivalent to those of the second predicate combination TENS/EMS device “Unipro (K-UNIPRO-US)” (K232441).

Differences between the proposed device and the primary predicate, and between the proposed device and the second predicate device, do not raise different questions of safety or effectiveness. The devices have a near-identical principle of operation, all involving the application of the device onto the intact skin at anatomical locations suitable for the identified clinical problem.