September 21, 2020

Medline Industries Inc
Leontyne Banks
Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60090

Re: K201290
Trade/Device Name: Medline DeNovo 4Pro Electrical Stimulation Device
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ, HCC, GZI, KPI
Dated: June 14, 2020
Received: June 24, 2020

Dear Leontyne Banks:

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,

Vivek Pinto, PhD
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201290

Device Name
Medline DeNovo 4Pro Electrical Stimulation Device

Indications for Use *(Describe)*

For EMG mode:
- Relaxation muscle training and muscle re-education

For NMES (also known as STIM) mode:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion
- Muscle Re-Education

For TENS mode:
- Symptomatic relief and management of chronic (long-term), intractable pain
- Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain

For EMG Triggered Stimulation (ETS) mode (nonimplanted electrical continence device only):

-Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscles through reflexive mechanisms and strengthening of pelvic floor muscles

-Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles (abdominal or gluteal)

For FES
- Helps to relearn voluntary motor functions of the extremities

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
[AS REQUIRED BY 21CFR807.92(c)]

Submitter / 510(k) Sponsor

Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093

Registration Number: 1417592

Contact Person

Leontyne Banks
Regulatory Specialist
Phone: 224-931-1484
Email: lbanks@medline.com

Summary Preparation Date

September 15, 2020

Type of 510(k) Submission

Traditional

Device Name / Classification

Proprietary Name: Medline DeNovo 4Pro Electrical Stimulation Device
Classification Name: Device, Biofeedback
Classification Panel: Neurology
Product Code: IPF, KPI, GZJ, HCC, GZI
Regulatory Class: Class II
Regulation #: 21 CFR 890.5850, 876.5320, 882.5890, 882.5050, 882.5810

Predicate Device

Primary Predicate: Otto Bock Healthcare Product GmbH – STIWELL med4 – K080950

Secondary Predicate: Thought Technology Ltd. – MyoTrac Infiniti Electrical Stimulator – K053434

Device Description

The Medline DeNovo 4Pro Electrical Stimulation Device is a four-channel, hand-held, non-sterile, battery-powered, multi-patient device intended to be used by adult patients under the supervision of a trained clinical healthcare provider. The proposed device is controlled by a MCU (Microcontroller Unit) that supports device functionality, display functionality, Bluetooth, and audio. The subject device is intended to be used for muscle stimulation for the purposes of urinary incontinence treatment, pain management, muscle strengthening and training, as well as muscle relaxation and re-education. The device is a TENS (Transcutaneous Electrical Nerve Stimulator), ETS (Electrical Muscle Stimulator) and NMES (Neuromuscular Electrical Stimulator also known as STIM) including FES (Functional Electrical Stimulation) with EMG biofeedback.

The Medline DeNovo 4Pro Electrical Stimulation Device features four channels for NMES (Neuromuscular Electrical Stimulator also known as STIM), with two that utilize Electromyography (EMG). Multiple stimulation protocols are pre-programed for three general categories of applications: muscle strengthening (i.e. biofeedback training), pain control, and neuromuscular re-education. Each category contains up to eight protocols to address the specific needs of the patient.

The Medline DeNovo 4Pro Electrical Stimulation Device is designed to provide safe and effective electrical stimulation by sending small electrical currents to underlying nerves and muscle groups via electrodes applied on the skin or through a vaginal probe (for incontinence treatment protocols only). The parameters of the unit are controlled by the +/- push buttons and touch screen (refer to Figure 1 and 2 below). The pre-programed protocols on the Medline DeNovo 4Pro Electrical Stimulation Device are all fully automatic and controlled by the device, and it is also capable of manual control in hand switch mode. The levels of intensity are adjustable to the needs of the patient and treatments prescribed by their healthcare providers. The device can be used with or without linkage to a PC and includes a color, pressure sensitive touch-screen. This unit also comes with a wireless charger that is capable of charging during NMES (Neuromuscular Electrical Stimulator also known as STIM) via inductive charging. Batteries will not need to be regularly replaced, and charging will be made so much easier. The proposed device also has Bluetooth capabilities that will allow the device to connect to a computer for screen mirror imaging.

How Device Achieves its Intended Purpose:

- TENS
  TENS uses the proposed battery operated unit to provide a non-invasive, low-risk nerve stimulation in order to reduce pain (both acute and chronic). In TENS, mild electrical impulses are transmitted through the skin via surface electrodes to relieve muscle pain by modifying the body's pain perception. TENS does not cure problematic physiological conditions; it only helps to control the pain perception.
- NMES (also known as STIM)
  NMES is the elicitation of muscle contraction using electric impulses. The impulses are

generated by a device and delivered through the electrodes in direct proximity to the muscles to be stimulated or via the vaginal probe. The impulses mimic the action potential coming from the central nervous system, causing the muscles to contract. NMES is both a form of electrotherapy and of muscle training. Neuromuscular Stimulation has been used to stimulate muscle and nerve fibers for muscle strengthening, maintenance of muscle mass and strength during prolonged periods of immobilization, selective muscle retraining, and the control of edema.

- FES
  FES is the process of combining electrical stimulation with a functional task such as walking. This is a treatment that applies small electrical charges to the leg to improve mobility in people who have difficulties with walking. As well as being a treatment for foot drop, FES can also be used in rehabilitation, complementing physiotherapy techniques, often to assist with movements in muscles that have become weak. This allows the user to build strength and range of movement.
- Surface electromyography (EMG)
  EMG is a technique for evaluating and recording the electrical activity produced by skeletal muscles. Surface EMG is used for recording from superficial muscles in clinical or kinesiological protocols, where intramuscular electrodes are used for investigating deep muscles or localized muscle activity.
- ETS
  ETS involves initiating a voluntary contraction for a specific movement until the muscle activity reaches a threshold level. This treatment is especially useful for stroke rehabilitation and pelvic muscle improvement. As soon as the EMG activity reaches a target threshold then an assisting electrical stimulus begins which helps to support the contracted muscle. A microprocessor connected to the surface electrodes or vaginal probe monitors the EMG activity levels as well as administers the neuromuscular stimulation. The Target threshold could be set to automated regime, when it goes up and down depending on the running muscle performance.

Figure 1: Medline DeNovo 4Pro Electrical Stimulation Device
The illustration below presents the Medline DeNovo 4Pro Electrical Stimulation Device.

Figure 2: Buttons and Basic Operation

The illustration below presents the keypad button functions for the Medline DeNovo 4Pro Electrical Stimulation Device. Please note that many of the button options below are duplicated by the touch screen buttons.

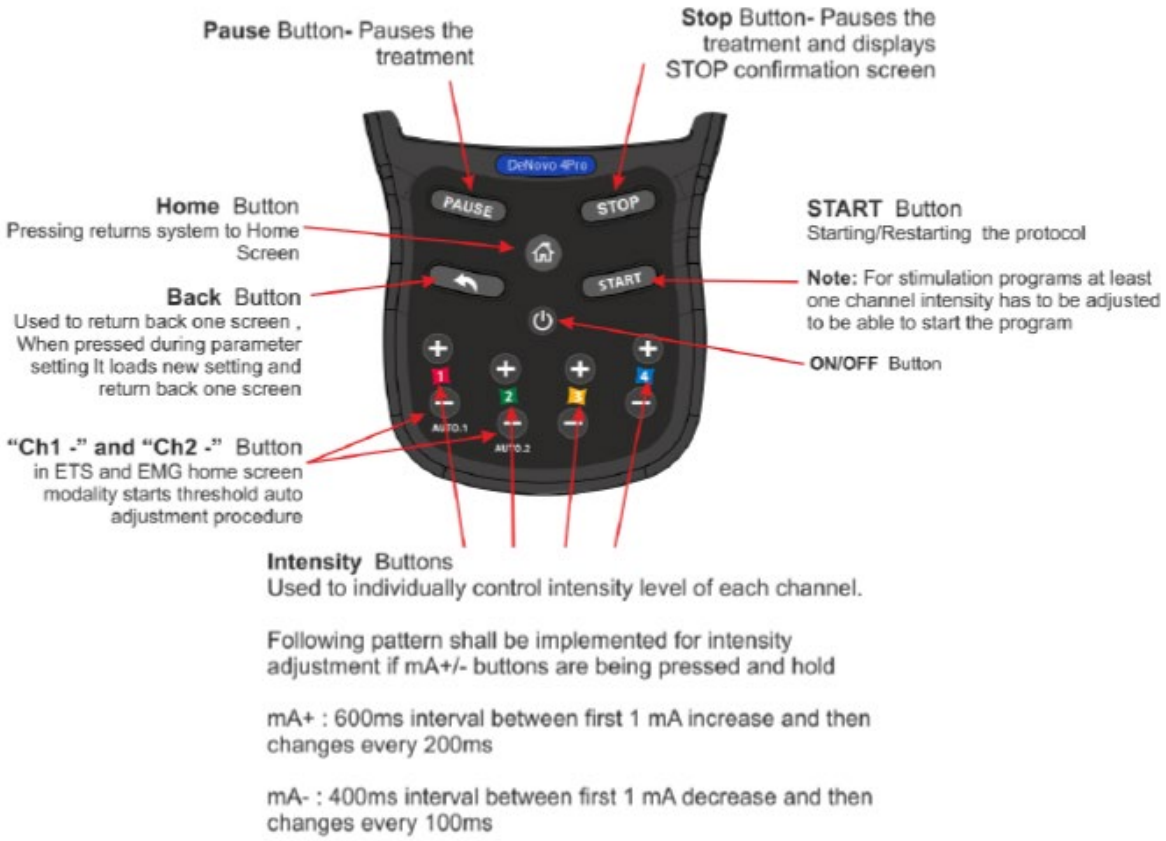
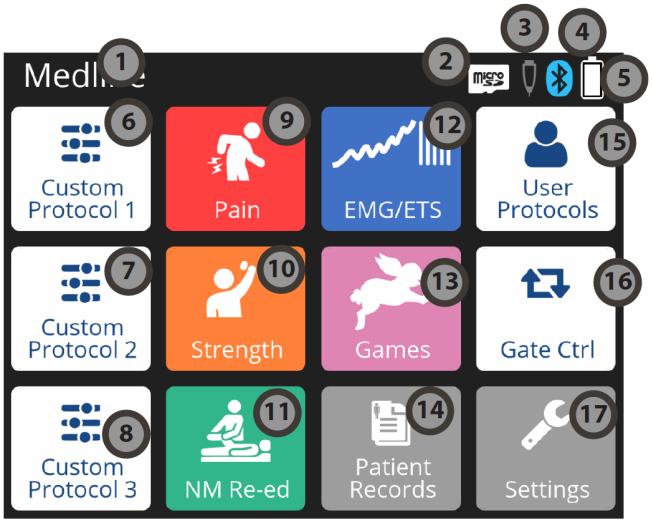


Figure 3: Buttons and Basic Operation
The illustration below presents the home touch screen functions of the Medline DeNovo 4Pro Electrical Stimulation Device. Please refer to DNV420P-SRS-P9 in Appendix E for additional screen settings and protocol options.



1. Device Name
2. MicroSD Card
3. Hand Switch Icon – Accesses the manual hand switch treatment mode
4. Bluetooth Icon – Accesses Bluetooth ID information
5. Battery Icon – Displays battery voltage levels
6. Custom Protocol shortcut 1 – Accesses most frequently used protocols (assigned by user)
7. Custom Protocol shortcut 2 – Accesses most frequently used protocols (assigned by user)
8. Custom Protocol shortcut 3 – Accesses most frequently used protocols (assigned by user)
9. System Pre-defined Protocols – Pain
10. System Pre-defined Protocols – Strength
11. System Pre-defined Protocols - Neuromuscular Re-education (NM Re-ed)
12. EMG/ET – EMG and ETS (EMG triggered stimulation) modality (including EMG template training)
13. Games – Accesses EMG games
14. Patient Records – Accesses patient information and records stored in Micro SD card (if card with data is inserted)
15. User Protocols – Accesses list of custom protocols created and saved by the user
16. Last Used – Accesses last used program
17. Global Settings – Accesses general device settings

Accessories

The proposed device is intended to come with eight electrodes and a vaginal probe. The electrodes offered with this device are manufactured by GMDASZ Manufacturing Co., Ltd and are covered under a separate 510(k) (K160138). Similarly, the vaginal probe is covered by its own 510(k) (K122194) and is manufactured by Everyway Medical Instrument Co. Ltd. Table 1 and 2 below provide additional information regarding these accessories.

Table 1: Accessory Description - Adhesive Electrodes

Device Name	Adhesive Electrodes
Product Code	GXY
Regulation Number	882.1320
Classification	II
510(k) Number	K160138
Device Description	Multi-layer reusable, flexible structures composed of laminated materials commonly used in this application. **First layer**: Insulating backing material: Fabric/foam/tan fabric **Second layer**: Conductive film: Carbon film/Carbon film coated with silver/aluminum foil film **Third layer**: Biocompatible self-adhesive conductive hydrogel Protective liner: PET
Intended Use	The adhesive electrodes are intended for as a reusable, conductive adhesive interface between the patient's skin and the marketed electrical stimulators (i.e. TENS (Transcutaneous Electrical Nerve Stimulation)), EMS (Electrical Muscular Stimulation), IF (Interferential) or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current.
Electrical Connection	Lead wire
Biocompatibility	Complies with ISO 10993
Single Use vs. Single Patient Use	Single Patient Use
Reusable vs. Disposable	Reusable
Prescription vs. OTC	Prescription Use and OTC Use

Table 2 Accessory Description: Vaginal Probe

Device Name	Everyway Incontinence Stimulation Electrode – Vaginal Stimulation
Product Code	HIR
Regulation Number	876.5320
Classification	II
510(k) Number	K122194
Device Description	The Life-Care Vaginal Probe models PR-02/02A, PR-03/03A, PR-04/04A, PR-10A, PR-h1A, PR-14A are light weight cylinders consisting of two or three independent conductive rings or plates that are paired and isolated, physically and electrically. The cylinder is shaped with a waist and handle for comfort positioning in vaginal canal for incontinent treatment as above mentioned and easy for removing after treatment. It is watertight to allow for washing with soap and water between uses. The electrode is designed for repeated intermittent use in home or clinic for up to one year by a single user. It does not require sterilization, but does required washing for reuse according to the validated cleaning method as recommended in user manual.
Intended Use	Intended to provide EMG feedback from pelvic musculature or electrical stimulation to pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control during the treatment of urinary incontinence.
Indications for Use	Electrical stimulation of the pelvic floor muscles for the treatment of urinary incontinence. EMG sensing of the pelvic floor muscles.
Electrical Connection	Lead wire
Biocompatibility	Conformity to ISO 10993-5 and ISO 10993-10
Single Use vs. Single Patient Use	Single patient use
Reusable vs. Disposable	Reusable
Prescription vs. OTC	Prescription Use

Intended Use

For EMG mode:

- Relaxation muscle training and muscle re-education

For NMES (also known as STIM) mode:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion
- Muscle Re-Education

For TENS mode:

- Symptomatic relief and management of chronic (long-term), intractable pain
- Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain

For EMG Triggered Stimulation (ETS) mode (nonimplanted electrical continence device only):

- Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscles through reflexive mechanisms and strengthening of pelvic floor muscles
- Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles (abdominal or gluteal)

For FES

- Helps to relearn voluntary motor functions of the extremities

Summary of Technological Characteristics

Tables 3 and 4 provides a side-by-side comparison between the proposed device and the selected predicate devices, the STIWELL med4 (K080950) and MyoTrac Infiniti Electrical Stimulator Device (K053434).

Table 3: COMPARISON OF PROPOSED AND PRIMARY PREDICATE DEVICES - STIWELL med4

Device Characteristic	Proposed Device Medline DeNovo 4Pro	Predicate Device #1 STIWELL med4 – K080950	Comparison Analysis
Product Name	Medline DeNovo 4Pro Electrical Stimulation Device	STIWELL med4	N/A
MANUFACTURER	Medline (Sponsor) Verity (Manufacturer)	Otto Bock Healthcare Product GmbH	N/A
510(k) REFERENCE	TBD	K080950	N/A
PRODUCT CODE	IPF KPI HCC GZJ GZI	IPF KPI HCC GZJ GZI	Same
CLASSIFICATION	Class II	Class II	Same
REGULATION NUMBER	21 CFR 890.5850 21 CFR 876.5320 21 CFR 876.5050 21 CFR 882.5890 21 CFR 882.5810	21 CFR 890.5850 21 CFR 876.5320 21 CFR 876.5050 21 CFR 882.5890 21 CFR 882.5810	Same
INDICATIONS FOR USE	NMES (also known as STIM) • Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing local blood circulation • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Maintaining or increasing range of motion • Muscle Re-Education For EMG Triggered Stimulation (ETS) mode (nonimplanted electrical continence device only): • Acute and ongoing treatment of stress, urge or mixed urinary incontinence and	As a powered muscle stimulator the STIWELL med4 is indicated for the following Conditions: • Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing local blood circulation • Muscle Re-Education • Maintaining or increasing range of motion • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis As a transcutaneous electrical nerve stimulator for pain relief the	Similar

	where the following results may improve urinary control: Inhibition of the detruser muscles through reflexive mechanisms and strengthening of pelvic floor muscles • Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles (abdominal or gluteal) TENS • Symptomatic relief and management of chronic (long-term), intractable pain • Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain EMG • Relaxation muscle training and muscle re-education FES • Helps to relearn voluntary motor functions of the extremities	STIWELL med4 is indicated for the following Conditions: • Symptomatic relief and management of chronic (long-term), intractable pain • Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain As a Biofeedback Device the STIWELL med4 id indicated for the following conditions: • Biofeedback, relaxation and muscle re-education purposes As an external functional neuromuscular stimulator the STIWELL med4 is indicated for the following conditions: • Helps relearn voluntary motor functions of the extremities As a non-implanted electrical continence device the STIWELL med4 is indicated for the following conditions: • Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detrusor muscles through reflexive mechanisms and strengthening of the pelvic floor muscles • Incontinence Treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal and the gluteus muscles	
PRESCRIPTION vs. OTC	Prescription Use	Prescription Use	Same
STERILE vs NON-STERILE	Non-Sterile	Non-Sterile	Same

WAVEFORMS	• Symmetrical Biphasic DC zero [TENS and HAN (TENS)] • Symmetrical Biphasic [NMES]	• Biphasic Symmetrical	Similar
CONNECTION OF DEVICE TO ELECTRODES	With cables including pins to connect to electrodes pins. There is 1 cable per channel with a maximum of 4 channels.	With cables including pins to connect to electrodes pins. There is 1 cable per channel with a maximum of 4 channels	Same
ENVIRONMENT OF USE	Physician Office, physical therapy clinic, hospital, nursing home, post-acute care, Chiropractic Clinic	Physician Office, physical therapy clinic, hospital, nursing home, post-acute care, Chiropractic Clinic	Same
TARGET POPULATION	Adult	Adult	Same
POWER SOURCE	4x AA NiMh, 4.8V Rechargeable Battery pack	Battery Pack Li-ion 11, 1V	Different
ELECTRICAL TYPE	Type BF	Type BF	Same
PATIENT LEAKAGE CURRENT – NORMAL CONDITION (µA)	N/A Battery Operated Device (<100 µA patient leakage)	N/A Battery Operated Device (<100 µA patient leakage)	Same
PATIENT LEAKAGE CURRENT – SINGLE FAULT CONDITION (µA)	N/A Battery Operated Device (<100 µA patient leakage)	N/A Battery Operated Device (<100 µA patient leakage)	Different
NUMBER OF OUTPUT MODES	Two: • **Muscle stimulator**: Electrodes • **TENS** (Transcutaneous electrical nerve stimulator): Electrodes	One	Different
NUMBER OF OUTPUT CHANNELS	Four	Four	Same
SYNCHRONOUS OR ALTERNATING	Synchronous and Alternating	Alternating	Similar
METHOD OF CHANNEL ISOLATION	Each channel is the middle of an H bridge. Each channel is in a high impedance state except when it is activated for a specific output pulse	Through transformer inductive couplers	Different
REGULATED CURRENT OR REGULATED VOLTAGE (OUTPUT SIGNALS ONLY)	Constant current on all four channels	Regulated Current	Similar
SOFTWARE/ FIRMWARE/ MICROPROCESSOR	Yes	Yes	Same

CONTROL			
AUTOMATIC OVERLOAD TRIP	No Device can withstand indefinite short circuit	Yes	Different
AUTOMATIC NO-LOAD TRIP	Yes	Yes	Same
AUTOMATIC SHUT OFF	Yes	Yes	Same
PATIENT OVERRIDE CONTROL	Yes	Yes	Same
INDICATOR DISPLAY **- ON/OFF STATUS** **- LOW BATTERY** **- VOLTAGE/ CURRENT LEVEL** **-BLUETOOTH** **-MICRO SD CARD**	Yes Bluetooth Connection MicroSD Card Insertion	Yes	Similar Proposed Device has Bluetooth Connection MicroSD Card Insertion
COMPLIANCE WITH VOLUNTARY STANDARDS	Yes • IEC 60601-1:2005+A1:2012 • IEC 60601-1-2 • IEC 60601-1-6 • IEC 60601-2-10 • FCC PART 15 Subpart B:2008 Class B • FCC CFR Title 47 Part 15 Subpart C	Yes • IEC 60601-1 • IEC 60601-1-2 • IEC 60601-2-10	Similar
COMPLIANCE WITH 21 CFR 898?	Yes, leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.	Yes, leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.	Same
WEIGHT	160 grams (0.35 lbs) without batteries and other accessories	Device: 440 grams	Different
DIMENSION (in.) [W X H X D]	3.78(96mm) x 6.30(160mm) x 1.42(36mm)	Device: 175 x 95 x 30 mm	Different
HAS VMS-FR WAVEFORM?	No – N/A	No – N/A	Same
HOUSING MATERIALS AND CONSTRUCTION	Plastic (Injection Molded ABS)	Plastic (Injection Molded ABS)	Same
NMES Symmetrical Biphasic Waveform / (VMS for STIWELL med4)			
SHAPE	• Symmetrical rectangular Biphasic [TENS and HAN (TENS)]	• Biphasic Symmetrical • Rectangular	Same

	• Symmetrical rectangular Biphasic [NMES]		
MAXIMUM OUTPUT VOLTAGE (± 10%)	45V @500Ω 70V @ 2kΩ 70V @ 10kΩ (open lead detected above 0.5 [mA])	50V @ 500 Ω 115V @ 2 kΩ N/A @ 10 kΩ	Different
MAXIMUM OUTPUT CURRENT (± 10%)	90mA @500Ω 35mA @ 2kΩ 7mA @ 10kΩ (open lead detected above 0.5 [mA])	100 mA @ 500 Ω 58 mA @ 2 kΩ N/A mA @ 10 kΩ	Different
PULSE WIDTH	50-450 µS in 10 µS step to 100 µS and thereafter 25 µS up to 450	50 to 400 [µs]	Different
FREQUENCY	2-100Hz in 1Hz steps from 2 to 20Hz thereafter in steps of 5Hz up to 100Hz	1 – 140 [Hz]	Different
NET CHARGE [µC/pulse]	0[µC] @ 500Ω	0 [µC] @ 500Ω	Same
MAXIMUM PHASE CHARGE [µC]	40.5[µC] @ 500Ω [90mA for 450µS]	40.0 [µC] @ 500Ω	Similar
MAXIMUM CURRENT (RMS) DENSITY (mA/cm2)	1.42mA /sq cm for electrode of 19sq cm	12.5 mA/cm2	Different
MAXIMUM POWER DENSITY [mW/cm²]	19[mW/cm2] @ 500Ω for Electrode of 19sq cm	7.9mW/cm^2	Different
ON TIME (SECONDS)	2 – 99 seconds	1 – 20 seconds	Different
OFF TIME (SECONDS)	2 – 99 seconds	1 – 50 seconds	Different
TREATMENT TIME (MINUTES)	2 – 99 minutes	2 – 120 minutes	Different
NUMBER OF CHANNELS	4	Up to 4	Same
TENS Waveform			
SHAPE	Symmetrical rectangular Biphasic [TENS and HAN (TENS)]	Biphasic Symmetrical	Same
MAXIMUM OUTPUT VOLTAGE (± 10%)	40V @ 500 Ω 70V @ 2 kΩ 70V @ 10 kΩ (open lead detected above 0.5[mA])	50V @ 500 Ω 115V @ 2 kΩ N/A @ 10 kΩ	Different
MAXIMUM OUTPUT CURRENT (± 10%)	80 mA @ 500 Ω 35mA @ 2 kΩ 7mA @ 10 kΩ (open lead detected above 0.5[mA])	100mA @ 500 Ω 58 mA @ 2 kΩ N/A @ 10 kΩ	Different
PULSE WIDTH	50-450 µS in 5µS steps	150µS, 200µS	Different
FREQUENCY	2-120Hz in 1Hz steps from 2 to 20Hz thereafter in steps of 5Hz up to 100Hz	2 – 100 [Hz]	Similar

BURST FREQUENCY	N/A	N/A	Same
AMPLITUDE MODULATION	N/A	N/A	Same
TREATMENT TIME (MINUTES)	0-99	10-20	Similar
FES Waveform			
SHAPE	Symmetrical rectangular Biphasic	Biphasic Symmetrical Rectangular	Same
MAXIMUM OUTPUT VOLTAGE (± 10%)	40V @ 500 Ω 70V @ 2 kΩ 70V @ 10 kΩ (open lead detected above 0.5[mA])	50V @ 500 Ω 115V @ 2 kΩ N/A @ 10 kΩ	Different
MAXIMUM OUTPUT CURRENT (± 10%)	90 mA @ 500 Ω 35mA @ 2 kΩ 7mA @ 10 kΩ (open lead detected above 0.5[mA])	100mA @ 500 Ω 58 mA @ 2 kΩ N/A mA @ 10 kΩ	Different
PULSE WIDTH	50-450 µS in 5µS steps	50 to 400 [µS]	Different
FREQUENCY	2-120Hz in 1Hz steps from 2 to 20Hz thereafter in steps of 5Hz up to 100Hz	1 – 140 [Hz] Default 35[Hz]	Different
BURST FREQUENCY	N/A	N/A	Different
AMPLITUDE MODULATION	N/A	N/A	Different
Incontinence Programs			
SHAPE	Symmetrical rectangular Biphasic	Biphasic Symmetrical Rectangular	Same
MAXIMUM OUTPUT VOLTAGE (± 10%)	40V @ 500 Ω 70V @ 2 kΩ 70V @ 10 kΩ (open lead detected above 0.5[mA])	50V @ 500 Ω 115V @ 2 kΩ N/A @ 10 kΩ	Different
MAXIMUM OUTPUT CURRENT (± 10%)	90 mA @ 500 Ω 35mA @ 2 kΩ 7mA @ 10 kΩ (open lead detected above 0.5[mA])	100mA @ 500 Ω 58 mA @ 2 kΩ N/A mA @ 10 kΩ	Different
PULSE WIDTH	50-450 µS in 5µS steps	500µS	Different
FREQUENCY	2-120Hz in 1Hz steps from 2 to 20Hz thereafter in steps of 5Hz up to 100Hz	10Hz	Different
BURST FREQUENCY	N/A	N/A	Same
AMPLITUDE MODULATION	N/A	N/A	Same
Biofeedback			
SHAPE	N/A	N/A	Same
MAXIMUM OUTPUT VOLTAGE (± 10%)	N/A	N/A	Same
MAXIMUM OUTPUT	N/A	N/A	Same

CURRENT (± 10%)			
PULSE WIDTH	N/A	N/A	Same
FREQUENCY	N/A	N/A	Same
BURST FREQUENCY	N/A	N/A	Same
AMPLITUDE MODULATION	N/A	N/A	Same
TREATMENT TIME (MINUTES)	2 – 99	5-30	Similar

Table 4: Comparison of Proposed and Secondary Predicate Device – MyoTrac Infiniti

Device Characteristic	Proposed Device Medline DeNovo 4Pro	Predicate Device #2 MyoTrac Infiniti – K053434	Comparison Analysis
DEVICE NAME	Medline DeNovo 4Pro Electrical Stimulation Device	MyoTrac Infiniti Electrical Stimulator	N/A
MANUFACTURER	Medline (sponsor) Verity (manufacturer)	Thought Technology Ltd.	N/A
510(k) NUMBER	TBD	K053434	N/A
PRODUCT CODE	IPF KPI HCC GZJ GZI	IPF KPI HCC	Similar
CLASSIFICATION	Class II	Class II	Same
REGULATION #	21 CFR 890.5850 21 CFR 876.5320 21 CFR 876.5050 21 CFR 882.5890 21 CFR 882.5810	21 CFR 890.5850 21 CFR 876.5320 21 CFR 876.5050	Similar
INDICATIONS FOR USE	NMES (also known as STIM) • Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing local blood circulation • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Maintaining or increasing range of motion	The MyoTrac Infiniti system is also indicated for the ongoing treatment of the following conditions (NMES mode): • Relaxation of Muscle Spasms, • Prevention or retardation of disuse atrophy, • Increasing local blood circulation, • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis	Similar

	• Muscle Re-Education For EMG Triggered Stimulation (ETS) mode (nonimplanted electrical continence device only): • Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscles through reflexive mechanisms and strengthening of pelvic floor muscles • Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles (abdominal or gluteal) TENS • Symptomatic relief and management of chronic (long-term), intractable pain • Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain EMG • Relaxation muscle training and muscle re-education FES • Helps to relearn voluntary motor functions of the extremities	• Maintaining or increasing range of motion • Stroke Rehab by Muscle re-education. • Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscle through reflexive mechanisms and strengthening of pelvic floor muscles. EMG Triggered Stim • Stroke Rehab by Muscle re-education. • Relaxation of Muscle Spasms, • Prevention or retardation of disuse atrophy, • Increasing local blood circulation, • Maintaining or increasing range of motion • Muscle re-education. • Stress, urge or mixed urinary incontinence by Inhibition of the detruser muscle through reflexive mechanisms and Strengthening of pelvic floor muscle EMG • Relaxation & Muscle Re-Education purposes • Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal or gluteal muscles. • Biofeedback	

POWER SOURCE	4X AA 1.5V Alkaline or rechargeable NiMH Battery	4X AAA 1.5V Alkaline or rechargeable NiMH Battery pack	Same
STIMULATOR OUTPUT	0-90mA	0-100mA	Similar
WAVEFORM	Symmetrical balanced biphasic rectangular pulsed current – DC zero	Asymmetrical Balanced Pulsed Current – DC zero	Different
CHARGE/PULSE AT 500 ohms	40.5µC (output pulse at max of 450µS width and 90mA)	60µC	Different
FREQUENCY	2-100Hz in 1Hz steps from 2 to 20Hz thereafter in steps of 5Hz up to 100Hz	12.5, 50, 100, 200 Hz	Similar
PEAK PULSE INTENSITY	90mA	100mA	Different
PULSE WIDTH	50-450 µS in 5µS steps	220 µS	Different
RAMPS	0.1 to 9.9 in steps of 0.1 seconds for both up ramp and down Ramp	0 – Duty Cycle on and off ramp	Different
DUTY CYCLE	On (sec): 2-99 Off (sec): 2-99	On (sec): 2 – 20 Off (sec): 2 – 50	Different
SESSION DURATION	1-99 minutes	1-120 minutes	Similar
PROGRAMMABLE FEATURES	Frequency, Current intensity, pulse width, ramp up and down, session length, by the patient and the physician. Physicians can lock the features for the patient with the exception of current intensity	Frequency, Current intensity, pulse width, ramp up and down, session length, by the patient and the physician. Physicians can lock the features for the patient with the exception of current intensity	Same
VAGINAL EMG/STIM PROBE	Everyway Incontinence Stimulation Electrode (Life-Care Vaginal Probe): K122194 Electrical stimulation of the pelvic floor muscles for the	1.Saint-Cloud Probe for vaginal muscle stimulation and Biofeedback, manufactured by Saint-Cloud International 2. Femelex Probe for vaginal Muscles stimulation and	Different

	treatment of urinary incontinence. EMG sensing of pelvic floor muscles.	Biofeedback manufactured by PhysioMed.	
VAGINAL EMG/PROBE	Everyway Incontinence Stimulation Electrode (Life-Care Vaginal Probe): K122194	Thought Technology Ltd. Vaginal Probe for EMG only K932149B	Different
ANAL EMG/STIMULATION PROBE	N/A proposed device does not include an anal probe	Saint-Cloud Probe for Rectal Muscle Stimulation and Biofeeback, manufactured by Saint-Cloud International	Proposed Device does not come with Anal Probe
CURRENT DENSITY RMS (FULL OUTPUT)	Everyway Incontinence Stimulation Electrode: 4.2mA/ cm2	St Cloud Vaginal: 6.76mA/cm2 Femelex Vaginal: 4.76 mA/cm2 St Cloud Rectal: 19.72mA/cm2	Proposed Device does not come with Anal Probe
POWER DENSITY (FULL OUTPUT @ 500 OHMS)	Everyway Incontinence Stimulation Electrode: 56mW/cm2	St Cloud Vaginal: 22.84 mW/cm2 Femelex Vaginal: 11.32 mW/cm2 St Cloud Rectal: 194 mW/cm2	Proposed Device does not come with Anal Probe
EMG RANGES IN µV	0 – 2000 in steps of 0.1µV to 20µV and thereafter steps of 1µV up to 2000µV	0-5, 0-10, 5-10, 0-20, 5-20, 10-20, 0-50, 10-50, 0-100, 50-100, 0-200, 50-200, 100-200, 0-500, 100-500, 0-1000, 0-2000	Similar
EMG BANDWIDTH	10- 370Hz	20-500 Hz	Similar
EMG SIGNAL PROCESSING	Root Mean Square (RMS)	Root Mean Square (RMS)	Same
EMG DETECTION	Bipolar	Bipolar	Same
WORK PERIOD (SEC)	2-99 second in steps of 1 second	2 – 20 seconds	Different
REST PERIOD (SEC)	2-99 second in steps of 1 second	2 – 50 seconds	Different
SESSION DURATION (MIN)	1-99 minutes	1 -120 minutes	Similar
FEEDBACK MODES	Line Graph, Bar Graphs, Digital Display, Signal linked Animations	Line Graph, Bar Graphs, Digital Display, Signal linked Animations	Same

Discussion of Similarities and Differences

STIWELL med4 (K080950) and MyoTrac Infiniti (K053434) were chosen as predicates to our proposed device due to the intended use, indications, performance, as well as the function and device specific testing that had been performed. To account for the minor variations listed within the above discussion, our basis for claiming substantial equivalence of the proposed device to the predicates has also been supported by a considerable amount of testing, including electrical safety and electronic compatibility, Software verifications/validations, and usability.

Summary of Non-Clinical Testing

Functional Performance Testing
Non-clinical verification of Medline DeNovo 4Pro Electrical Stimulation Device was conducted to evaluate the safety, performance, and functionality of this device. The results of these tests demonstrate the overall safety of the subject device and ultimately support a substantial equivalence determination. For additional information, please refer to Appendix D.

In summary, performance testing was conducted to demonstrate the safety and effectiveness of the subject device in accordance with the relevant standards cited below:

Electrical Safety and Electronic Compatibility:

- IEC 60601-1: 2012 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 Medical Electrical Equipment – Part 1 - 2: General requirements for basic safety and essential performance - Electromagnetic disturbances – Requirements and tests
- IEC 61000-6-1: Electromagnetic compatibility EMC – Part 6-1: Generic standards – Immunity for residential, commercial and light-industrial environments
- IEC 60601-2-10: 2012 Medical Electrical Equipment – Part 2-10: Particular Requirements for the Basic Safety and Essential Performance of Nerve and Muscle Stimulators
- IEC 60601-2-40: 1998 Particular Requirements for safety-electromyographs and evoked response equipment

FCC Radio Frequency (RF) Testing

- FCC/CFR 47: Part 15.2018, subpart B: 2008 Class B ANSI C63.4: 2003
- FCC/CFR 47: Part 15: 2018, subpart C – internal radiators: Federal Code of Regulations (CFR) requirements for internal radiators

Wireless Coexistence Testing
In accordance with the requirements of FDA's guidance document: Radio Frequency Wireless Technology in Medical Devices the Medline DeNovo 4Pro Electrical Stimulation Device was evaluated in an environment with other Medline DeNovo 4Pro Electrical Stimulation devices and with other types of 2.4 GHz wireless devices (Wi-Fi) in order to ensure the subject device functions in the presence of multiple, coexisting communication systems simultaneously.

Usability Testing

- IEC 60601-1-6:2013 Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
- IEC 62366:2007 Medical Devices - Application of Usability Engineering to Medical Devices *
  *This standard is cited in IEC 60601-1-6

Software Testing
The Medline DeNovo 4Pro Electrical Stimulation Device complies with the with the standard, IEC 62304:2015 Medical Device Software – Software Life Cycle Processes. Additionally, the subject device is classified as Class B software. Software verification and validation activities have been conducted on the subject device in accordance with the FDA guidance document, General Principles of Software Validation as described below.

Software Verification
Testing was designed to demonstrate the software meets its design requirements in accordance with the requirements of FDA's guidance document: General Principles of Software Validation, January 11, 2002.

Software Validation
Testing was designed to demonstrate that the software specifications conform to user needs, intended uses, and that the particular requirements implemented through software can be consistently fulfilled. In addition, the proposed software validation plan and report provides evidence that all software requirements have been implemented correctly and completely and is traceable to system requirements.

Biocompatibility Testing
The Medline DeNovo 4Pro Electrical Stimulation Device itself has no direct or indirect contact with the patient. The accessory devices described in the section above would be the primary patient-contacting components, as they have direct contact with the patient at the treatment site. These devices are covered separately under their own respective 510(k) submissions, which include applicable biocompatibility testing; therefore, Medline did not perform biocompatibility testing on the final finished device or the patient-contacting accessories.

Summary of Clinical Testing
This section does not apply

Summary of Animal Testing
This section does not apply. No animal testing was performed.

Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the Medline DeNovo 4Pro Electrical Stimulation Device is substantially equivalent for their intended use as the predicate device STIWELL med4 (K080950) and MyoTrac Infiniti system (K053434).