June 26, 2025

Verity Medical Ltd.
Nigel Verity
Managing Director
Churchtown House
Tagoat, Co. Wexford Y35 XY44
IRELAND

Re: K243079
Trade/Device Name: NeuroTrac® MyoPlus Pro (MYO120U)
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: II
Product Code: KPI, HCC
Received: May 20, 2025

Dear Nigel Verity:

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,

Jessica K. Nguyen -S

Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243079

Device Name
NeuroTrac® MyoPlus Pro (MYO120U)

Indications for Use *(Describe)*
STIM
Electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in adult women.
EMG
Relaxation muscle training and muscle re-education.
ETS
Treatment of stress, urge or mixed urinary incontinence by assessing EMG activity of the pelvic floor and strengthening pelvic floor muscles using electrical stimulation.

This device is intended to be used by adult woman (aged above 22 years).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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TRADITIONAL 510(K) SUMMARY

1. SUBMITTER INFORMATION

Applicant	Verity Medical Ltd. Churchtown House Tagoat, Co. Wexford Ireland Y35 XY44
Applicant Contact	Nigel C. Verity, Managing Director E-mail: nigel@veritymedical.com Phone: +353 (0) 53 913 2433
Date Prepared	June 23, 2025

2. DEVICE NAME

Trade Name of the Device	NeuroTrac® MyoPlus Pro (MYO120U)
Classification Name:	Nonimplanted electrical continence device
Classification Regulation:	21 CFR 876.5320
Device Class:	II
Product Code:	KPI, HCC
Panel:	Gastroenterology/Urology

3. PREDICATE DEVICES

	510(k)#	Trade Name
Primary Predicate	K083704	NuTrac Pelvator, model PEL 200
Secondary Predicate	K201290	Medline DeNovo 4Pro Electrical Stimulation Device

Predicate devices were not subjected to any design related recall.

4. DEVICE DESCRIPTION:

The NeuroTrac® MyoPlus Pro is a single-channel pelvic floor muscle stimulator (STIM) designed to assist patients with urinary incontinence to increase muscle control and overcome pelvic muscle dysfunction. It can also act as an electromyograph (EMG) and features an EMG-triggered stimulation (ETS) mode. The stimulation waveform is symmetrical, rectangular and biphasic. Stimulation is delivered using a vaginal probe. The vaginal probe included with the subject device was cleared under K122194. The subject device may either be operated directly by the prescribing physician, or by the patient as instructed by the physician.

5. INDICATIONS FOR USE:

STIM
Electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in adult women.
EMG
Relaxation muscle training and muscle re-education.
ETS
Treatment of stress, urge or mixed urinary incontinence by assessing EMG activity of the pelvic floor and strengthening pelvic floor muscles using electrical stimulation.

This device is intended to be used by adult woman (aged above 22 years).

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

Device & Predicate Device(s):	K243079 (Subject)	K083704 (Primary Predicate)	K201290 (Secondary Predicate)
Device name (Sponsor)	NeuroTrac® MyoPlus Pro (Verity Medical)	NuTrac Pelvator (Verity Scientific)	Medline DeNovo 4Pro Electrical Stimulation Device (Medline Industries)
Indication for use	**STIM** Electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in adult women. **EMG** Relaxation muscle training and muscle re-education. **ETS** Treatment of stress, urge or mixed urinary incontinence by assessing EMG activity of the pelvic floor and strengthening pelvic floor muscles using electrical stimulation. This device is intended to be used by adult woman (aged above 22 years).	The "nutrac pelvator" pelvic muscle trainer is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress urge and mixed urinary incontinence in women.	For EMG mode: - Relaxation muscle training and 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 detrusor 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)
Prescription Only	Yes	Yes	Yes

Home Use	Yes	Yes	Yes
Power Source(s)	4xAAA Alkaline, 6V	9v alkaline battery	4xAA niMH, 4.8V Rechargeable battery Pack
Program duration	15-45 mins (based on the programs) Adjustable: 1-99 mins	15-45 mins (based on the programs) Adjustable: 1-99 mins	5-60 mins (based on the programs) Adjustable: 1-99 mins
No. of Output Channels	For stimulation: 1 For EMG: 2	2	2
Applied Parts	Vaginal Probe and Skin electrode	Vaginal Probe	Vaginal Probe and Skin electrode
Current or Voltage Regulated	Constant current	Constant current	Constant current
Waveform	Biphasic	Biphasic	Biphasic
Shape	Symmetrical rectangular	Symmetrical rectangular	Symmetrical rectangular
Maximum Output Voltage (V)	45 V @ 500 Ω 103 V @ 2 kΩ 170 V @ 10 kΩ	45 V @ 500 Ω 103 V @ 2 kΩ 170 V @ 10 kΩ	40V @ 500 Ω 70V @ 2 kΩ 70V @ 10 kΩ
Frequency	2 Hz – 100 Hz	2 Hz – 100 Hz	2 Hz – 100 Hz
Net Charge (µC per pulse)	0 [µC] @ 500Ω	0 [µC] @ 500Ω	0 [µC] @ 500Ω
Maximum Output Current (mA)	90 mA @ 500 Ω 50 mA @ 2 kΩ 19 mA @ 10 kΩ	90 mA @ 500 Ω 50 mA @ 2 kΩ 19 mA @ 10 kΩ	90 mA @ 500 Ω 35 mA @ 2 kΩ 7mA @ 10 kΩ
Maximum Current Density (mA/cm²)	12.73 mA/cm^2 (with electrode surface area of 7.07 cm^2)	14.1 mA/ cm^2 (with electrode surface area of 6.4 cm^2)	1.42mA /cm^2(with electrode surface area of 19 cm^2)
Maximum Power Density @ 500 Ω	37.81mW/cm^2 for electrode surface area of 7.07 cm^2	41.8 mW/ cm^2 for electrode of 6.4 cm^2	19[mW/ cm^2] for electrode of 19 cm^2

The sponsor used the primary predicate to support the STIM mode of the subject device and used the secondary predicate to support the EMG and ETS modes of operation of the subject. As evidenced by the above table, the subject and the predicate devices have the same intended use but differ in technological characteristics. Performance testing was conducted on the subject device, and it was established that the differences in technological characteristics do not raise different questions of safety or effectiveness.

7. SUMMARY OF NONCLINICAL TESTING:

Below is a list of the tests that were performed and successfully completed for the subject device per the specified guidance and standards:

- Electrical Safety testing according to IEC 60601-1: 2020 - *Medical electrical equipment* –

Basic safety and essential performance

- Electromagnetic Compatibility testing according to IEC 60601-1-2: 2020 - *General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests*

- Software Verification and Validation Testing according to FDA's Guidance "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*"

- Cybersecurity risk management activities according to FDA Guidance *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, issued September 27, 2023*

Additionally, the values of net charge, maximum phase charge and maximum power density of the subject device were calculated under 500Ω load from the output stimulation waveforms to establish performance of the subject device.

All pre-determined acceptance criteria were met.

8. CONCLUSION

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicate devices.