August 2, 2024

SunMed LLC.
Robert Yamashita
VP of Regulatory Affairs
2710 Northridge Dr. NW, Suite A
Grand Rapids, Michigan 49544

Re: K233098
Trade/Device Name: MYOTouch Muscle Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: June 14, 2024
Received: June 14, 2024

Dear Robert Yamashita:

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,

Xiaorui Tang

For: CDR Jitendra Virani
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.

Submission Number *(if known)*

K233098

Device Name

MYOTouch Muscle Stimulator

Indications for Use *(Describe)*

The MYOTouch Muscle Stimulator is indicated for use as an adjunct in the treatment of high and low anorectic malformations by helping with the identification of striated muscles to be used in anal reconstructions. The MYOTouch device is intended for use by trained personnel who are competent to apply the appropriate stimuli.

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
K233098

Date of Submission Prepared: 11 November 2023

I Submitter:

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E-Mail: ryamashita@sun-med.com
Official Contact: Robert Yamashita / VP of Regulatory Affairs
FDA Establishment Registration No: 1314417

Address of the manufacturing facility:
EasyMed Instruments Co Ltd
3/F-6F, Block A, No. 4, Fengxin Road,
Fengxiang Industrial District, Daliang, Shunde,
Foshan, Guangdong, 528300 China
FDA Establishment Registration No: 3004049909

II Submitted Device:

Trade Name:	MYOTouch
Common Name:	Powered Muscle Stimulator Device
Regulation Name:	Powered Muscle Stimulator
Regulation Number:	21 CFR 890.5850
Product Code:	IPF
Classification Panel:	Physical Medicine
Device Class:	Class II

III Predicate Device:

Trade / Device Name:	Digitimer DS7AP Constant Current Stimulator
Submitter:	Digitimer Ltd
510(k) Number:	K172381
Regulation Name:	Powered Muscle Stimulator
Regulation Number:	21 CFR 890.5850
Product Code	IPF
Classification Panel:	Physical Medicine
Device Class:	Class II

IV Device Description:

MYOTouch is a hand-held device designed to be used for surgical correction of neonatal anorectal malformations. MYOTouch is intended for prescription use.

The device is a 9V battery-powered, one-channel muscle stimulator. The device is supplied with a Sterile Stylus, which connects to the control unit by cable and plug. The MYOTouch muscle stimulator has been specially designed to meet the requirements of pediatric surgeons who need a reliable and easy to use muscle locating stimulator when carrying out the Pena, "Pull-through", or posterior sagittal anorectoplasty (PSARP) anorectal reconstruction technique.

A trained professional or pediatric surgeon must use the MYOTouch device. The pediatric surgeon uses manual, push-button controls to control the electrical stimulation level. The unit is intended for prescription use and is designed with simplicity and ease of use. It has two preset modes available.

Intended Patient Population
The reconstruction surgeries for which the MYOTouch is intended are typically performed in newborns, infants, children, and adolescents (<18 years of age). Philip K. Frykman, M.D., Ph.D., M.B.A., FACS, FAAP confirm the intended patient population.

The intended population for the MYOTouch device is as listed below:

- Neonate/Newborn (birth through 28 days)
- Infant (from 29 days to 2 years of age)
- Child (from 2 years to 12 years of age)
- Adolescent (from 12 years to 18 years of age)

Intended Part of the Body to be Interacted With
The MYOTouch is used in the treatment of anorectal malformations by helping identify striated muscles to be used in anal reconstructions.

Intended User Profile
The intended user is a specialist clinician trained in neurophysiological studies or a pediatric surgeon trained in the specialist reconstruction surgeries for which the MYOTouch is indicated for.

Accessories:

- MS200 – Sterile Stylus specifications:
  - MYOTouch Frykman-Kimble Stimulator Stylus part number = MS200
- Replacement battery specifications:
  - 9 Volt Alkaline battery

ENVIRONMENT OF USE: Clinics, Hospital
The MYOTouch Muscle Stimulator is intended for static tabletop use in a clinical environment, typically a neurosurgery operating theatre.

V Indications for Use of the device:

The MYOTouch Muscle Stimulator is indicated for use as an adjunct in the treatment of high and low anorectic malformations by helping with the identification of striated muscles to be used in anal reconstructions. The MYOTouch device is intended for use by trained personnel who are competent to apply the appropriate stimuli.

VI Equivalence Comparison to the Predicate Devices:

Electrical muscle stimulation is the technological principle for the MYOTouch and the predicate device Digitimer DS7AP (K172381).

The intended Patient Population of MYOTouch is different from those of the predicate device Digitimer DS7AP (K172381), including individuals 3 – 18 years of age. Both devices have included the highest risk population, i.e., Neonate/Newborn (birth through 28 days), Infant (from 29 days to 2 years of age), and children <3 Years. Therefore, the difference does not raise new questions of safety or effectiveness.

The technical characteristics of MYOTouch are similar to those of the predicate device in design, intended use, and function. The new device MYOTouch and predicate device Digitimer DS7AP (K172381) apply an electrical current via a disposable bipolar probe to a patient's striated muscles.

The stimulation parameters of MYOTouch are similar to those of the predicate device Digitimer DS7AP (K172381). MYOTouch has two programs, and the parameters of MYOTouch are all in the similar range as those of the predicate device DS7AP (K172381).

Table 1 below summarizes the shared and unique technological elements between the MYOTouch and DS7AP (K172381).

Table 1 Substantial Equivalence Comparison Table

Attribute	Subject Device	Predicate Device	Comparison
Product Name	MYOTouch	Digitimer DS7AP	
Submitter	SunMed L.L.C.	Digitimer Ltd	
510(K) number	K233098	K172381	
Product Code	IPF	IPF	Identical
Regulation No.	21 CFR 890.5850	21 CFR 890.5850	Identical
Device Classification	Class II	Class II	Identical

Attribute	Subject Device	Predicate Device	Comparison
Indications for Use	The MYOTouch Muscle Stimulator is indicated for use as an adjunct in the treatment of high and low anorectal malformations by helping with the identification of striated muscles to be used in anal reconstructions. The MYOTouch device is intended for use by trained, competent personnel to apply the appropriate stimuli.	The Digitimer DS7AP Constant Current Stimulator is indicated for use as an adjunct in the treatment of high and low anorectal malformations by helping in the identification of the striated muscles to be used in anal reconstructions.	Similar. The subject device includes the intended user population in the indications for use statement
Intended Use	Used to identify striated muscle in the treatment of high and low anorectal malformations	Used to identify striated muscle in the treatment of high and low anorectal malformations	Identical
Prescription or Over-the-Counter	Prescription Use	Prescription Use	Identical
Number of output channels	One	One	Identical
Regulated Current or Regulated Voltage?	Yes, Constant Current	Yes, Constant Current	Identical
Software/Firmware/ Microprocessor Control?	Yes	No	Different See Note 1
Automatic No-Load Trip?	Yes	Yes	Identical
Automatic Overload Trip?	Yes	Yes	Identical
Automatic Shut Off?	No	No	Identical
User Override Control?	Yes	Yes	Identical
Indicator Display: -On/Off status	Yes Yes Yes	Yes N/A Yes	Similar See Note 2

Attribute	Subject Device	Predicate Device	Comparison
-Low battery -Voltage /Current level -Time to cut off	No	No	
Mode of Operation	2	2	Identical
Frequency	50Hz	50Hz	Identical
Pulse Width	200μs / 500μs	200μs (LO) / 500μs (HI)	Identical
Waveform	Mono-phasic	Mono-phasic	Identical
Shape	Rectangular	Rectangular	Identical
Maximum Output Voltage	56V@ 500Ω	56V@ 500Ω	Identical
Maximum Output Current	112mA@ 500Ω	112mA@ 500Ω	Identical
Maximum Phase Charge	56μC@ 500Ω	56μC@ 500Ω	Identical
Probe Diameter	1.44mm	0.73mm	Different See Note 3
Contact Surface Area	0.033cm^2	0.0084cm^2	Different See Note 3
Maximum Current Density	3.44A/cm^2 @ 500Ω	13.52A/cm^2@ 500Ω	Similar See Note 3
Maximum Power Density	4.96 W/cm^2@ 500Ω	18.93W/cm^2@ 500Ω	Similar See Note 3
Power Source	One 9V alkaline battery	Supply Mains (115/230V; 50/60Hz)	Different See Note 2
Dimensions [W x H x D]	113 x 61 x 25mm	255 x 100 x 225 mm	Similar The differences in device dimensions do not raise new questions about safety or effectiveness.
Weight	154g with battery(0.34lb)	2400g(4.85lb)	Similar The difference in device weight does not raise new questions about

Attribute	Subject Device	Predicate Device	Comparison
			safety or effectiveness.
Housing Materials and Construction	A.B.S. plastics	Thermo-plastic with metal front and rear panels	Different The difference in the housing material does not raise any additional safety and effectiveness problems. The subject device was tested per ISO 10993-1, with passing results.
Electrode lead wires and patient cable compliance with 21 CFR 898	Yes	Yes	Identical
Footswitch	NA	Yes	The predicate device (DS7AP) uses a footswitch to control the delivery of stimulation, while MYOTouch uses buttons on the main unit to control stimulation delivery. This difference does not raise new questions about safety or effectiveness.
Compliance with Voluntary Standards	Yes See section 1, 1.3 Comparisons of Applied Standards	Yes See section 1, 1.3 Comparisons of Applied Standards	Identical
Operator Interaction: Functions Controllable: An explanation of how the device interacts	The operator can control the electrical stimulation levels, the starting and stopping stimulation.	The operator can control the electrical stimulation levels and the starting and stopping stimulation.	Identical

Attribute	Subject Device	Predicate Device	Comparison
with the operator.			
Operator Interaction: Programming Capability Whether the device can be programmed and to what extent	The operator sets electrical stimulation levels. Operators can choose between two stimulation modes.	The operator sets electrical stimulation levels. Operators can choose between two stimulation modes.	Identical
Operator Interaction: Operator Requirements Knowledge and training required of the operator	Prescription device. Special knowledge and training are required; a detailed instruction manual is provided	Prescription device. Special knowledge and training are required; a detailed instruction manual is provided	Identical

Different Technological Characteristics:

1. Software Control: MYOTouch uses a microprocessor to control the generation of desired outputs, while Digitimer DS7AP utilizes logical and analog circuits to generate outputs. The subject device is a complete digital device and gives the operator more accurate control and outputs.

2. Power Supply: Subject device MYOTouch uses a 9V battery as its power supply, while predicate device Digitimer DS7AP is A.C. main powered. The subject device provides the similar effective output characteristics of electrical pulses, compared to the predicate device. The subject device is much smaller in size, weight, and portability. Both devices are in compliance with IEC 60601-1 requirements. The differences in power source do not raise new questions about safety or effectiveness.

3. Stimulation Parameters: The stimulation parameters of the new device MYOTouch are the similar as those of the predicate device Digitimer DS7AP (K172381). MYOTouch has two modes, single and continuous pulse outputs, while Digitimer DS7AP (K172381) also has two modes, Low (200μs) and High (500μs), both being continuous output pulses.

The new device, MYOTouch, offers the operator a single pulse output, which reduces risk to the patient because it uses minimum output energy application to achieve the similar muscle stimulation outcomes.

The subject device's probe is larger in diameter compared to the predicate device, offering a greater contact surface area. The current and power densities are lower for the subject device when the same current intensity level is chosen.

The power densities of both the predicate and subject device are greater than the recommended 0.25 W/cm^2 limit (per the FDA Guidance Document on Powered Muscle Stimulators) at certain stimulation level settings. Warnings have been added to the subject device's labelling to provide similar risk mitigations provided in the predicate device.

4. Mode of Operation: MYOTouch has two modes, single and continuous pulses outputs, while Digitimer DS7AP also has two modes, Low (200μs) and High (500μs), both being continuous output pulses. The new device, MYOTouch, offers the operator a single pulse output, which is safer for the patient because it uses minimum output energy application to achieve the similar muscle stimulation outcomes.

5. Housing Materials and Construction: MYOTouch has a complete A.B.S. plastic housing, while the predicate device uses Thermoplastic with metal front and rear panels. The housing material does not contact the patient. The subject device was tested per ISO 10993-1, with passing results. These differences in housing material and construction does not raise new concerns about safety and effectiveness in their intended use.

VII Performance Tests:

A series of safety and performance tests were conducted on the subject device MYOTouch. See below:

FDA recognition No.	Standard Title
19-49	IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
19-36	I.E.C. 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
17-16	I.E.C. 60601-2-10 Edition 2.1 2016-04 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
5-125	ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices
13-79	IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes

All the test results demonstrate that MYOTouch meets the requirements of its predefined acceptance criteria and intended use.

VIII Clinical Tests

No clinical tests were submitted to support this 510(k)

X Conclusion:

- The MYOTouch has similar technological characteristics and intended uses as the predicate Digitimer DS7AP (K172381), and
- The labeling of the MYOTouch is concordant with the predicate device and FDA requirements, and
- The technological differences between subject device MYOTouch and predicate device DS7AP does not raise new questions about safety or effectiveness. It demonstrates with reasonable assurance based on established controls that the device is at least as safe and effective as the legally marketed predicate device.

Therefore, the MYOTouch is substantially equivalent to the predicate device.