May 5, 2021

Ito Co., Ltd.
Takeshi Kobayashi
Manager
3-1-8 Sakae-cho
Kawaguchi-shi, Saitama 332-0017
Japan

Re: K203525
Trade/Device Name: D function
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NUW
Dated: April 2, 2021
Received: April 5, 2021

Dear Takeshi Kobayashi:

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,

For Michael Adjodha
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*

K203525

Device Name
D function

Indications for Use *(Describe)*

1) To relieve symptoms associated with muscle spasm, to treat temporomandibular joint (TMJ) dysfunction and associated pain
2) Muscle re-education
3) Increasing blood flow
4) Maintain or increase mandibular 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 (K203525)

D function

I. SUBMITTER

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Contact Person: Takeshi Kobayashi
Date Prepared: 05/04/2021

II. DEVICE

Name of Device:	D function
Common name:	Stimulator, Muscle, Powered, Dental
Regulation Number	890.5850
Classification Name:	Stimulator, Muscle, Powered, Dental
Regulatory Class:	II
Product Code:	NUW

III. PREDICATE DEVICE

PRIMARY PREDICATE DEVICE: MODEL J-5 MVO-MONITOR, K031998
REFERENCE DEVICE: TRIO 300, K990787

IV. DEVICE DESCRIPTION

This device is a current stimulation device with Therapeutic Electro Muscle Stimulator function. Power is supplied by the built-in rechargeable lithium battery or AC adapter. The stimulation current generated by the output circuit of the main body is supplied to the user through the electrode cord and the electrode to realize current stimulation. The device is equipped with PAIN mode, CARE mode and MCR mode. Each CH can output independently and be adjusted. If it outputs in CARE mode, it can be used for both outputs at the same time.

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V. INDICATION FOR USE

1) To relieve symptoms associated with muscle spasm, to treat temporomandibular joint (TMJ) dysfunction and associated pain

2) Muscle re-education

3) Increasing blood flow

4) Maintain or increase mandibular range of motion

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The legally marketed predicate device and the legally marketed reference device were selected for comparison to the D function, regarding substantial equivalence.

The main different specifications between the predicate device and the proposed device are described as below;

	Proposed Device	Predicate Device	Differences
Pulse Width	PAIN: 150 μs CARE: 488 μs MCR: 150 ms	488 μs	The pulse width of MCR mode of the proposed device is longer than the pulse width of the predicate device.
Output Frequency (Hz)	PAIN: 200 CARE: 0.67 MCR: 400	0.67	The frequency of the PAIN mode and MCR mode of the proposed device are higher than the frequency of the predicate device.
Output Current	PAIN: 80 mA CARE: 24 mA MCR: 750 μA	-24 mA	The current of PAIN mode of the proposed device is higher than the output current of the predicate device.

As shown in the table above, since the specifications of the proposed device and the predicate device are different, the reference device including fully specification ranges of the proposed device was indicated to support the substantial equivalence.

The proposed device is substantial equivalent to the predicate device and the reference device, when each mode of the proposed device are used for the equivalent intended use of the predicate device or reference device, corresponding to intended use of each modes.

伊藤超短波株式会社 MANUFACTURERS & EXPORTERS

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Feature/Description	Proposed Device	Primary Predicate Device	Reference Device
Model Number	D function	Model J-5 Myo-Monitor	TRIO 300
Manufacturer	ITO CO., LTD.	Myotronics-Noromed, Inc.	ITO CO., LTD.
Regulatory Background			
FDA 510(k) Number	K203525	K031998	K990787
Device Type	Stimulator, Muscle, Powered, Dental	Stimulator, Muscle, Powered, Dental	Stimulator, Muscle, Powered Stimulator, Nerve, Transcutaneous, For Pain Relief
FDA Product Code	NUW	NUW	IPF, GZJ
FDA Regulatory Class	II	II	II
FDA Authorized Use	Prescription Use	Prescription Use	Prescription Use
Patient Therapy			
Indications for Use	1) To relieve symptoms associated with muscle spasm, to treat temporomandibular joint (TMJ) dysfunction and associated pain 2) Muscle re-education 3) Increasing blood flow 4) Maintain or increase mandibular range of motion	Used to relieve symptoms associated with muscle spasm, to treat temporomandibular joint (TMJ) dysfunction and associated pain, to relax muscles and establish a physiologic occlusion, to take occlusal registrations, to take denture impressions, to increase local blood circulation and to increase or maintain mandibular range of motion.	Trio300 is indicated for the symptomatic relief of chronic intractable pain, treatment of post-traumatic and post-surgical pain, relaxation of muscle spasm, prevention or retardation of disuse muscle atrophy, muscle reeducation, increase local blood circulation, maintain or increase range of motion, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
Physical Design			
Physical Dimensions (in.) [W x H x D]	3.3 x 0.93 x 5.9	6.5x 2.56 x 6.97	2.7 x 0.98 x 4.4
Gross Weight	230 g	480 g	185 g
Accessory Attachment Method	Pad	Pad	Pad
Electrical Design			
Electrical Safety & EMC Testing	ANSI AAMI ES60601-1, IEC 60601-1-2,	unknown	IEC 60601-1, IEC 60601-1-2

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Feature/Description	Proposed Device	Primary Predicate Device	Reference Device
	IEC 60601-2-10		
Electrical Safety Class	Class II internally powered equipment, Type BF	Internally powered equipment, Type BF	Class II internally powered equipment, Type BF
Power Supply	DC 7.4 (Lithium ion battery) DC 12 V (AC adaptor) AC 100-240V, 50/60Hz	DC 9V (battery)	DC 9V (battery) DC 9V (AC adaptor) AC 120V, 60 Hz
Electrical input power	30 VA	-	420 mA
Output Specification			
Pulse Width	PAIN: 150 µs CARE: 488 µs MCR: 150 ms	488 µs	250 ms
Output Frequency (Hz)	PAIN: 200 CARE: 0.67 MCR: 400	0.67	400
Output Current	PAIN: 80 mA CARE: 24 mA MCR: 750 µA	-24 mA	80 mA
Pulse Shape	rectangular	rectangular	rectangular
Channel Numbers	2	4	2
Other Functions			
Timer	Yes	No	Yes
Buzzer	Yes	No	Yes
LCD	Yes	Yes	Yes

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VII. PERFORMANCE DATA

Cited Standards to Determine Substantially Equivalence:

D function complies with the following FDA recognized:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 Medical electrical equipment – Part1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment – Part1-2: General requirements for basic safety and essential performance – Collateral standard Electromagnetic phenomena – Requirements and tests
- IEC 60601-2-10 Edition 2.1 2016-04 Medical electrical equipment – Part2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

Non-clinical Testing:

Non-clinical verification and validation testing was conducted on D function device.

The verification results demonstrate that the proposed device complies with the standard, IEC62304:2006/ Amd.1: 2015 Medical device software - Software life cycle processes. Additionally, the proposed device meets its design requirements in accordance with the requirements of FDA's guidance documents: Guidance for the Content of Premarket Submissions for Software.

The validation results demonstrate that the software specifications conform to user needs and intended uses, and that the particular requirements implemented through the proposed device can be consistently fulfilled. In addition, the proposed validation plan, procedure, testing and result provides evidence that all requirements have been implemented correctly and completely and is traceable to system requirements.

VIII. CONCULUSION

The non-clinical data support the substantial equivalence of the proposed device to the declared predicates and the hardware and software verification and validation demonstrate that the D function device should perform as intended in the specified use conditions.