October 21, 2022

Medlander Medical Technology Inc.
% Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, Guangdong 518067
China

Re: K222201
Trade/Device Name: Biological Feedback and Stimulation System
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, KPI, HCC
Dated: July 7, 2022
Received: July 25, 2022

Dear Kevin Wang:

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,

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
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

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)*
K222201

Device Name
Biological Feedback and Stimulation System

Indications for Use *(Describe)*
As a powered muscle stimulator the Biological Feedback and Stimulation System is indicated for thefollowing conditions:
- Relaxation of muscle spasm
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

As a biofeedback device the Biological Feedback and Stimulation Systemis indicated for thefollowing conditions:
- Biofeedback, relaxationand muscle re-education purposes

As a nonimplanted electrical continence device the Biological Feedback and Stimulation Systemisindicated 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 pelvic floor muscles.
- Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal and the gluteus muscles.

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

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2022/7/18

1. Submission sponsor

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2. Submission correspondent

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Contact person: Kevin Wang
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3. Subject Device Information

Trade/Device Name	Biological Feedback and Stimulation System
Model	MLD M2R, MLD M2A, MLD M2B, MLD M2D, MLD M4R, MLD M4D, MLD M4E, MLD M4Plus
Common Name	Powered muscle stimulator Non-implantable electrical continence device Biofeedback device
Regulatory Class	Class II
Regulation number	21 CFR 890.5850 21 CFR 876.5320 21 CFR 882.5050
Product code:	IPF, KPI, HCC
Review panel	Physical Medicine Gastroenterology/Urology Neurology
Submission type	Traditional 510(K)

4. Predicate Device

Shenzhen Konmed Technology Co., Ltd., Biofeedback Nerve and Muscle Stimulator under

K202648.

5. Device Description

This Biological Feedback and Stimulation System is a new type of biofeedback and neuromuscular electrical stimulation therapy device through the evaluation of myoelectric signal acquisition, multimedia biofeedback training, electromyography triggered electrical stimulation, passive electrical stimulation training and treatment.

6. Intended use & Indication for use

As a powered muscle stimulator the Biological Feedback and Stimulation System is indicated for the following conditions:

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

As a biofeedback device the Biological Feedback and Stimulation System is indicated for the following conditions:

- Biofeedback, relaxation and muscle re-education purposes

As a nonimplanted electrical continence device the Biological Feedback and Stimulation System 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 pelvic floor muscles.
- Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal and the gluteus muscles.

7. Comparison to the Predicate Device

Features	**Subject Device: Biological Feedback and Stimulation System (K222201)**	**Predicate Device: Biofeedback Nerve and Muscle Stimulator (K202648)**	**Comparison**
Product Code	IPF, KPI, HCC	IPF, KPI, HCC	Same
Regulation Number	21 CFR 890.5850 21 CFR 876.5320 21 CFR 882.5050	21 CFR 890.5850 21 CFR 876.5320 21 CFR 882.5050	Same

Classification	Class II	Class II	Same
Type of use	Prescription	Prescription	Same
Indications for Use	As a powered muscle stimulator the Biological Feedback and Stimulation System is indicated for the following conditions: ● Relaxation of muscle spasm ● Prevention or retardation of disuse atrophy ● Increasing local blood circulation ● Muscle re-education ● Immediate post- surgical stimulation of calf muscles to prevent venous thrombosis ● Maintaining or increasing range of motion As a biofeedback device the Biological Feedback and Stimulation System is indicated for the following conditions: ● Biofeedback, relaxation and muscle re-education purposes As a nonimplanted electrical continence device the Biological Feedback and Stimulation System 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 pelvic floor muscles. ● Incontinence treatment for assessing EMG activity of the pelvic floor and accessory	As a powered muscle stimulator the Biofeedback Nerve and Muscle Stimulator is indicated for the following conditions: ● Relaxation of muscle spasm ● Prevention or retardation of disuse atrophy ● Increasing local blood circulation ● Muscle re-education ● Immediate post- surgical stimulation of calf muscles to prevent venous thrombosis ● Maintaining or increasing range of motion As a biofeedback device the Biofeedback Nerve and Muscle Stimulator is indicated for the following conditions: ● Biofeedback, relaxation and muscle re-education purposes As a nonimplanted electrical continence device the Biofeedback Nerve and Muscle Stimulator 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 detruser muscles through reflexive mechanisms and strengthening of pelvic floor muscles. ● Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal	Same

	muscles such as the abdominal and the gluteus muscles.	and the gluteus muscles.	
Patient population	Adult	Adult	Same
Basic unit specification			
Power supply	14.8VDC, 5Ah rechargeable lithium battery	7.4V DC/1200mAh rechargeable lithium battery	Different
Method of Line Current Isolation	N/A	N/A	Same
Leakage current – Normal condition - Single fault condition	N/A (Battery)	N/A (Battery)	Same
Number of output modes	4	2	Different
Number of output channel	4	2	Different
Software/ Firmware/ Microprocessor control	Yes	Yes	Same
Automatic Overload trip	Yes	Yes	Same
Automatic no-load trip	Yes	Yes	Same
Patient override control method	Yes	Yes	Same
Indicator display -On/Off status -Low battery -Output mode -Time to cutoff -Voltage/current level	Yes	Yes	Same
Automatic Shut Off	Yes	Yes	Same
Timer range	1min～60min, adjustable	1-99min, adjustable	Different

Dimensions	280mm × 280mm × 110mm	KM530: 140.5×25.5×69mm KM531: 146.5×29×74mm	Different
Weight	2Kg	KM530: 192 g KM531: 230g	Different
Housing material and construction	Plastic	Plastic	Same
Compliance with voluntary standards	IEC 60601-1; IEC 60601-1-2; IEC 60601-2-10; IEC 60601-2-40	IEC 60601-1; IEC 60601-1-2; IEC 60601-2-10; IEC 60601-1-11; IEC 60601-2-40	Similar
Compliance with 21CFR 898	Yes	Yes	Same
Output specifications			
Waveform	Pulsed biphasic，The positive wave is rectangular and the negative wave is spike	Pulsed symmetric, asymmetric, biphasic square wave	Different
Maximum output voltage	50V@500Ω，error：±20%; 145V@2KΩ，error：±20%; 226V@10KΩ，error：±20%	47.2V @ 500Ω 108V @ 2kΩ 150V@ 10kΩ	Similar
Maximum output current	100mA@500Ω，error：±20%; 72.5mA@2KΩ，error：±20%; 22.6mA@10KΩ，error：±20%	94.4mA @ 500Ω 54mA @ 2kΩ 15mA@ 10kΩ	Similar
Net Charge (per pulse)	≤3.5μC @500Ω	For pulsed symmetric, biphasic: 0μC @500Ω; For pulsed asymmetric, biphasic: 15.68μC @ 500Ω	Similar
Maximum Phase Charge (500Ω)	≤11.5μC @500Ω	51.4μC @ 500Ω	Similar
Maximum current density (500Ω)	≤17.5 mA/cm²@500Ω	6.01mA/ cm2@ 500Ω	Similar

Maximum power density (500Ω)	≤0.01W/cm²@500Ω	0.012W(12mW) / cm2@ 500Ω	Similar
Pulse frequency	0.5Hz-1000Hz	2-100Hz	Similar
Pulse duration	10μs～1000μs	50-450μs	Similar
Biofeedback performance			
Number of EMG channel	2	2	Same
EMG detection (bipolar/ monopolar)	Bipolar	Bipolar	Same
EMG range (μV)	1-3000μV	0.2-2000μV	Similar
EMG bandwidth	20Hz-550Hz	20Hz-500Hz	Similar

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the proposed device was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The battery of testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Vaginal and rectal irritation

Non-clinical data

Non-clinical testing has been conducted to verify that the Biological Feedback and Stimulation System meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device. The testing results demonstrate that the targeted device complies with the following standards:

- IEC 60601-1, Medical electrical equipment -- Part 1: General

requirements for basic safety and essential performance

- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances – Requirements and tests
- IEC 60601-2-10, Medical electrical equipment -- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 60601-2-40, Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment

We have also conducted:

- Software verification and validation test according to the requirements of the FDA "Guidance for Pre-Market Submissions and for Software Contained in Medical Devices"
- The waveform test report has also been conducted to verify the output specifications of the device according to Guidance Document for Powered Muscle Stimulator 510(k)s

9. Conclusion

Performance testing and compliance with voluntary standards demonstrate that the proposed subject device is substantially equivalent to the predicate device.