December 8, 2020

Shenzhen Konmed Technology Co., Ltd.
% Tracy Che
Registration Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90,
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K202648
Trade/Device Name: Biofeedback Nerve and Muscle Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, KPI, HCC
Dated: September 7, 2020
Received: September 11, 2020

Dear Tracy Che:

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 Heather Dean, PhD
Assistant Director
DHT5B: Division of Physical Medicine- Acute Injury 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202648

Device Name
Biofeedback Nerve and Muscle Stimulator (Model: KM530, KM531)

Indications for Use *(Describe)*
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 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

K202648

This "510(k) Summary" of 510(k) safety and effectiveness information is submitted in accordance with requirements of Title 21, CFR Section 807.92.

(1) Applicant information:

510(k) owner's name:	Shenzhen Konmed Technology Co., Ltd.
Address:	601, Building B4, Shenchengtou Creative Factory Life Science Park, Julongshan A Road, Xiuxin Block, Kengzi Street, Pingshan District, Shenzhen, Guangdong, CHINA, 518118
Contact person:	Shuishan Yin
Title	General manager
Phone number:	+86 755 8670 4556
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Email:	2519021651@qq.com
Date of summary prepared:	December 3, 2020

(2) Reason for the submission

New device, there were no prior submissions for the device.

(3) Proprietary name of the device

Trade name/model:	Biofeedback Nerve and Muscle Stimulator/ KM530, KM531
Common name:	Powered muscle stimulator Non-implantable electrical continence device Biofeedback device
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
Regulation class:	Class II

(4) Predicate and reference device

- **Predicate device**

Sponsor	Otto Bock Healthcare Product GmbH

Device Name and Model	STIWELL med4/ Model: 900101S
510(k) Number	K080950
Product Code	IPF, GZI, KPI, GZJ, HCC
Regulation Number	21 CFR 890.5850 21 CFR 876.5320 21 CFR 882.5050 21 CFR 882.5890 21 CFR 882.5810
Regulation Class	II

- **Reference device**

Sponsor	Thought Technology Ltd	Mantra International (HK) Ltd
Device Name and Model	MyoTrac Infiniti System	Kegel8
510(k) Number	K053434	K081480
Product Code	IPF, KPI, HCC	KPI
Regulation Number	21 CFR 890.5850 21 CFR 882.5050 21 CFR 876.5320	21CFR876.5320
Regulation Class	II	II

(5) Description/ Design of device:

This Biofeedback Nerve and Muscle Stimulator 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.

There are two models of Biofeedback Nerve and Muscle Stimulator which are KM530 and KM531. Their intended use, working principle, product structure and major parameters are all same, apart from the difference of product appearance, and KM531 has several more programs than KM530.

The device is battery-powered with a display screen and offers the user a choice of EMG Test (Only for EMG acquisition, not for electrical stimulation), EMG Game (6 biofeedback response-based vivid games, active training for the user to contract the muscles of the treatment area, no electrical stimulation is generated), ETS (electromyography triggered stimulation; Only when the EMG value reaches the set threshold, the electrical stimulation is triggered; This module is a combination of active and passive treatment module, which exercise the self-contracting ability of the user), and STIM (Neuromuscular stimulation with fixed programs and customized programs of which parameters can be adjusted under the directions of physicians or professionals).

The device is supplied with vaginally inserted probe used with the device to stimulate the muscle of the pelvic floor (the probe is identical to that used in the model KM518 with 510(k) number

K163288). Anal probe is optional, user can choose to purchase qualified probe. The device is supplied with biofeedback reference lead wire with skin electrodes. The device main unit connects directly to the vaginal electrode and reference wire by cable and plug. The device provides independent dual-channel EMG signals acquisition and dual-channel electrical stimulation output which is convenient for the treatment of different sites.

(6) Indications for use:

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 and the gluteus muscles.

(7) Materials

Component name	Material of Component	Body Contact Category	Contact Duration
Electrode patches	Three layers: 1. Insulation backing material: Fabric/Foam/Tan fabric 2. Conductive film: Carbon film/Carbon film coated with silver/Aluminum foil film	Surface-contacting device: Intact skin	Less than 24 hours

	3. Conductive hydrogel (A, T or U gel)		
Vaginal probe	ABS plastic, stainless steel	Surface-contacting device: Mucosal membrane	Less than 24 hours

We have selected 510(k) cleared electrode patches to be used with our device, its 510(k) number is K160138 (model: OCWN2505), and its biocompatibility complies with ISO 10993. The vaginal probe is the same probe with that used in another model KM518 manufactured by our company, which has already obtained 510(k) number K163288 on 01/18/2018, biocompatibility test reports were submitted during that application. For details, please refer to "Biocompatibility Discussion".

(8) Technological characteristics and substantial equivalence:

Item	Targeted device	Predicate device 1	Reference device 1	Reference device 2	Remark
Trade name	Biofeedback Nerve and Muscle Stimulator	STIWELL med4/ Model: 900101S	MyoTrac Infiniti System	Kegel8	/
510 (k) number	K202648	K080950	K053434	K081480	/
Manufacturer	Shenzhen Konmed Technology Co., Ltd	Otto Bock Healthcare Product GmbH	Thought Technology Ltd	Mantra International (HK) Ltd	/
Regulation number	21 CFR 890.5850 21 CFR 876.5320 21 CFR 882.5050	21 CFR 890.5850 21CFR876.5320 21CFR882.5050 21CFR882.5890 21CFR882.5810	21 CFR 890.5850 21 CFR 882.5050 21CFR876.5320	21CFR876.5320	Same
Regulation description	Powered muscle stimulator; Nonimplanted electrical continence device;Biofeedback device	Powered muscle stimulator; Nonimplanted electrical continence device;Biofeedbackdevice; Transcutaneouselectricalnervestimulatorforpainrelief;Externalfunctionalneuromuscularstimulator	Powered muscle stimulator;Biofeedbackdevice; Nonimplanted electrical continence device	Non-implanted electrical continence device	Same
Product code	IPF, KPI, HCC	IPF, KPI, HCC, GZJ,GZI	IPF, HCC, KPI	KPI	Same
Class	II	II	II	II	Same

Indications for use/ Intended use	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	The STIWELL med4 is a neuromuscular electronic stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions. As a powered muscle stimulator the STIWELL med4 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 transcutaneous electrical nerve stimulator for pain relief the STIWELL med4 is indicated for the followingconditions: · Symptomatic relief and management of chronic (long-term), intractable pain · Adjunctive	The MyoTrac Infiniti system is indicated for acute and ongoing treatment ofstress, urge or mixed urinary incontinence and where the following results mayimprove urinary control: Inhibition of the detruser muscle through reflexive mechanisms, strengthening of pelvic floor muscle. It is also indicated duringincontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal or gluteal muscles. The MyoTrac Infiniti system is also indicated for the ongoing treatment of thefollowing conditions: Relaxation ofMuscle Spasms, Prevention or retardation of disuse atrophy, increasing local blood circulation, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, Maintaining or increasingrange of	The 'Kegel8' 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.	Similar, the indications for use of the targeted device is within that of the predicate device

	Stimulator is indicated for the followingconditions : · 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 accessorymuscles such as the abdominal and the gluteus muscles	treatment in the management of post-surgical pain and post traumatic acute pain. As a biofeedback device the STIWELL med4 is 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 to relearn voluntary motor functions of the extremities As a nonimplanted electrical continence device the STIWELL mad4 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	motion and Stroke Rehab by Muscle re-education. Itis also used for Biofeedback, Relaxation & MuscleRe-Education purposes.		

		· Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal and the gluteus muscles			
Patient population	Adult	Adult	Adult	Adult	Same
Location for use	Prescription	Prescription	Prescription	Prescription	Same
Basic unit specification					
Power supply	7.4V DC/1200mAh rechargeable lithium battery	Battery Pack Li-lon 11.1V	4X AAA 1.5 Alkaline or rechargeable NiMH Battery pack 6VDC-15W Medical Class II power adapter	9V PP3	Different **Note 1**
Method of Line Current Isolation	N/A	Medical Class II Power Adapter	N/A	N/A- Battery powered	Same
Leakage current - Normal condition - Single fault condition	N/A (Battery)	N/A (Battery)	N/A	N/A- Battery powered	Same
Number of output modes	2	1	/	1	Different **Note 2**
Number of output channel	2	4	/	2	Same
- Synchronous or Alternating?	Synchronous	Alternating		Synchronous/ Alternating	Similar
Method of channel isolation	Transformer	Transformer, inductive couplers	/	Individually isolated circuits	Same
Software/ Firmware/	Yes	Yes	Yes	Yes	Same

Microprocessor Control?					
Automatic Overload trip	Yes	Yes	/	Not publicly available	Same
Automatic no-load trip	Yes	Yes	/	Not publicly available	Same
Patient override control method	Yes	Yes (Stop Button)	/	Not publicly available	Similar
Indicator display -On/Off status -Low battery -Output mode -Time to cut-off -Voltage/ current level	Yes	Yes	/	Yes	Same
Automatic Shut Off	Yes	Yes	/	Yes	Same
Timer range	1-99min, adjustable	2-120min	/	Up to 90	Similar
Dimensions	KM530: 140.5×25.5×69mm KM531: 146.5×29×74mm	175×95×30mm	/	6.2cm W x 2.3cm D x 10.8cm H [2.4'' W x 0.9'' D x 4.25'' H]	Different **Note 3**
Weight	KM530: 192 g KM531: 230g	440g	/	0.07 Kg without battery, 0.1KG with battery	Different **Note 3**
Housing material and construction	Plastic	Plastics	/	/	Same
Compliance with voluntary standards	IEC 60601-1; IEC 60601-1-2; IEC 60601-2-10; IEC 60601-1-11; IEC 60601-2-40	IEC 60601-1; IEC 60601-1-2; IEC 60601-2-10	IEC 60601-1; IEC 60601-1-2; IEC 60601-2-10	IEC 60601-1; IEC 60601-1-2; IEC 60601-2-10	Same
Compliance with 21CFR 898	Yes	Yes	Yes	Yes	Same

Output specifications					
Waveform	Pulsed symmetric, asymmetric, biphasic square wave	Pulsed symmetrical, rectangular wave	Asymmetrical Balanced Pulsed Current	Biphasic, Rectangular	Similar
Maximum output voltage	47.2V @ 500Ω 108V @ 2kΩ 150V@ 10kΩ	50V@500Ω 115V@2kΩ N/A	/	45V @ 500Ω 100V @ 2kΩ 190V @ 10kΩ	Similar Within the range of predicate device
Maximum output current	94.4mA @ 500Ω 54mA @ 2kΩ 15mA@ 10kΩ	100mA@500Ω 58mA@2kΩ N/A	100mA	90mA @ 500Ω 50mA @ 2kΩ 19mA @ 10kΩ	Similar Within the range of predicate device
Net Charge (per pulse)	For pulsed symmetric, biphasic: 0μC @ 500Ω; For pulsed asymmetric, biphasic: 15.68μC @ 500Ω	0μC @ 500Ω	/	0 [μC] @ 500Ω	Similar **Note 4**
Maximum Phase Charge (500Ω)	51.4μC @ 500Ω	EMS: 40μC @500Ω Incontinence: 50μC @ 500Ω	60μC	40.5μC @ 500Ω	Similar
Maximum current density (500Ω)	6.01mA/ cm^2@ 500Ω	EMS: 12.5mA/cm^2@ 500Ω Incontinence: 4.7mA/cm^2@ 500Ω	St-Cloud Vaginal 6.76mA/cm^2 Femelex Vaginal 4.76mA/cm^2 St-Cloud Rectal 19.72mA/cm^2	14.1 [mA/cm^2]	Similar
Maximum power density (500Ω)	0.012W(12mW) / cm2@ 500Ω	EMS: 7.9mW/cm^2@ 500Ω (0.0079W/cm^2@ 500Ω) Incontinence: 23.5μW/cm^2@ 500Ω	St-Cloud Vaginal 22.84mW/cm^2 Femelex Vaginal 11.32mW/cm^2 St-Cloud Rectal 194mW/cm^2	57 [mW/cm^2] At maximum frequency of 100Hz, pulse width 450μS and current of 90mA PC Electrode area: 6.4 cm^2	Similar

Pulse frequency	2-100Hz	1-140Hz	12.5,50,100,200Hz	2 to 100Hz	Similar
Pulse duration	50-450μs	50-400μs	0.2ms	50 to 450 [μsec] Program dependent	Similar
Biofeedback performance					
Number of EMG channel	2	2	2	/	Same
EMG sampling rate	3kHZ	3kHz	/	/	Same
EMG detection (bipolar/ monopolar)	Bipolar	Bipolar	Bipolar	/	Same
EMG range (μV)	0.2-2000μV	1-2000μV	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	20Hz-500Hz	70-480Hz	20Hz-500Hz	/	Same
EMG signal processing	Root mean square (RMS)	AVR (Average Rectified Value)	Root mean square (RMS)	/	Same

Comparison in details:

Note 1: The targeted device uses lithium battery for power supply which is the same as the predicate device, although the voltage of the two batteries are different, the lithium battery used in the targeted device has been tested according to IEC 62133, so this difference should not raise any problems.

Note 2: The number of output modes are defined by the manufacturer, although it's different from that of the predicate device, the output parameters are similar to that of the predicate device, so this difference should not raise safety and effectiveness problem.

Note 3: Although the appearance, weight and dimensions are different between the targeted and predicate device, these differences are insignificant and do not raise any problems.

Note 4: Although the parameter is different from that of the predicate device, the targeted device has passed IEC 60601-1 and IEC 60601-2-10, so this difference should not affect safety and effectiveness.

Conclusion:

Biofeedback Nerve and Muscle Stimulator is substantially equivalent to the predicate devices.

(9) Non-clinical studies and tests performed:

Non-clinical testings have been conducted to verify that the Biofeedback Nerve and Muscle Stimulator 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:

- ANSI AAMI ES 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 60601-1-11, Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- 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

The body-contacting components of this device are electrode patches and vaginal probe. For these components, FDA 510(k) clearance and test reports have been provided. So we have reason to believe that the electrode patches and vaginal probe are safe for the users. They comply with the following standards.

- ISO 10993-5, Biological Evaluation of Medical Devices -- Part 5: Tests for InVitro Cytotoxicity
- ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.

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

(10) Conclusion

Based on the above analysis and tests performed, it can be concluded that the performance and function of Biofeedback Nerve and Muscle Stimulator are normal, it is Substantially Equivalent (SE) to the predicate device.