July 20, 2022

Shenzhen Konmed Technology Co.,Ltd.
℅ Cassie Lee
Manager
Guangzhou Glomed Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road,
Huangpu District
Guangzhou, Guangdong 510530
China

Re: K220161
Trade/Device Name: Biofeedback Nerve and Muscle Stimulator,
Models: KM530B, KM531B, KM536, KM537
Regulation Number: 21 CFR§ 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: II
Product Code: KPI, HCC
Dated: June 14, 2022
Received: June 21, 2022

Dear Cassie Lee:

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
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)*
K220161

Device Name
Biofeedback Nerve and Muscle Stimulator, Models: KM530B, KM531B, KM536, KM537

Indications for Use *(Describe)*
The device 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 and to maintain urinary continence in women.

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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510 (k) Summary

1.Submitter Information

510 (k) submitter:	Shenzhen Konmed Technology Co., Ltd.
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Contact Person's Fax Number:	+86 755 8670 4556
Preparation date:	July 19, 2022

Application Correspondent

Contact Person Name:	Ms. Cassie Lee
Contact Title:	Manager, Guangzhou GLOMED Biological Technology Co., Ltd.
Contact Person's email:	regulatory@ glomed-info.com
Contact Person's Phone Number:	+86 20 8266 2446

2.Device Information

Trade Name of the Device:	Biofeedback Nerve and Muscle Stimulator, Models: KM530B, KM531B, KM536, KM537
Common Name:	Nonimplanted electrical continence device
Classification Name:	Nonimplanted electrical continence device, Biofeedback Device
Classification Number:	21 CFR 876.5320, 21 CFR 882.5050
Regulatory Class:	II
Review Panel	Gastroenterology/Urology, Neurology
Product Code	KPI, HCC

3.Predicate Devices

510(k) number	K202648
Trade name of the Device	Biofeedback Nerve and Muscle Stimulator

The predicate has not been subjected to a design-related recall.

4.Device Description

The Biofeedback Nerve and Muscle Stimulator (Model: KM530B, KM531B, KM536, KM537) is a type of biofeedback and neuromuscular electrical stimulation therapy device for patients with pelvic floor muscle dysfunction. Through the evaluation of myoelectric signal acquisition, multimedia biofeedback training, electromyography triggered electrical stimulation, passive electrical stimulation training and treatment it helps to strengthen weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women.

The device is battery-powered with a touch screen Liquid Crystal Display (LCD) and offers the user a choice of electromyography (EMG) triggered stimulation (ETS) mode (The device provides a passive pulse stimulation when the level of active contraction of the pelvic floor muscles reaches a threshold by means of electrical feedback from the pelvic floor muscles. 17 (KM536, KM537) or 22 (KM530B, KM531B) pre-set sow-frequency pulses stimulate pelvic floor muscles Electrical Stimulation (STIM) programs with 6 pre-set biofeedback response-based EMG games and the EMG therapy are available for the users. The differences between the model KM530B and KM536 are only the model's name and the number of STIM Programs. The differences between the model KM531B and KM537 are also only the model's name and the number of STIM Programs.

5.Intended Use

The device 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 and to maintain urinary continence in women.

6.Comparison of The Technological Characteristics with Predicate Device:

	K220161 (Subject)	**K202648 (Predicate)**
Device Name	Biofeedback Nerve and Muscle Stimulator	Biofeedback Nerve and Muscle Stimulator
Indication For Use	The device 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 and to maintain urinary continence in women.	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.
Prescription or OTC	OTC	R_X Only
Power source	7.4V DC/1200mAh rechargeable lithium battery	7.4V DC/1200mAh rechargeable lithium battery
Maximum Output Current (±10%)	94.4mA @ 500Ω 54mA @ 2kΩ 15 mA @ 10kΩ	94.4mA @ 500Ω 54mA @ 2kΩ 15mA@ 10kΩ
Maximum Phase Charge	51.4μC@500Ω	51.4μC @ 500Ω
Maximum Current Density	6.01mA/ cm^2@ 500Ω Surface = 15.7 cm^2	6.01mA/ cm^2 @500Ω
Maximum Power Density	0.2814mW/ cm^2@ 500Ω	0.2814mW(12mW) / cm^2@ 500Ω
Frequency (Hz)	2-100Hz	2 -100Hz
Pulse Duration (μsec)	50-450μs	50- 450 μs
Net charge	For pulsed symmetric, biphasic: 0μC @ 500Ω;	For pulsed symmetric, biphasic: 0μC @ 500Ω;

As evidenced by the above table, both the subject and the predicate devices have the same intended use. Additionally, the subject device has identical technological characteristics to the predicate except the predicate device was cleared for prescription only use and the subject device is an over the counter (OTC) use device. However, this difference does not raise different questions of safety or effectiveness and the testing mentioned below showed that the subject is substantially equivalent with the predicate.

7. Performance Data

In support of this premarket notification, Shenzhen Konmed Technology conducted the following safety and performance testing on the subject device–

- Electrical safety test according to IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
- Electromagnetic compatibility test according to 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*
- Performance testing according to 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*
- Biocompatibility test according to ISO 10993-1, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
- Performance test according to IEC 60601-2-10, *Medical electrical equipment -- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and*

muscle stimulators

- Usability Study according to IEC 60601-1-6, *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability* and IEC 62366-1, *Medical devices - Part 1: Application of usability engineering to medical devices*

- Software verification and validation test according to the FDA guidance document "*Guidance for Pre-Market Submissions and for Software Contained in Medical Devices"*

All testing results confirmed that the products described in this submission met the necessary specification.

8. Conclusion

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