June 18, 2026

Shenzhen Konmed Technology Co., Ltd.
% Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Bldg. 1, Rui Feng Center
Kaichuang Rd., Huangpu District
Guangzhou, 510000
CHINA

Re: K260178
Trade/Device Name: Pelvic Muscle Trainer (KM510, KM516B)
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: II
Product Code: KPI
Dated: May 19, 2026
Received: May 19, 2026

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 (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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JESSICA K. NGUYEN -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260178

Please provide the device trade name(s).

Pelvic Muscle Trainer (KM510, KM516B)

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).	☐ Prescription Use (21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

For

Pelvic Muscle Trainer
Model: KM510, KM516B

Date of the summary prepared: June 16, 2026

510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

Company Name: Shenzhen Konmed Technology Co.,Ltd.
Establishment Registration Number: 3011905669
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Contact Person (including title): Tony (Project Manager)
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Application Correspondent:

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Guangzhou GLOMED Biological Technology Co., Ltd.
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Tel: +86 20 8266 2446
Email: regulatory@glomed-info.com

2. Subject Device Information

Trade Name: Pelvic Muscle Trainer
Model: KM510, KM516B
Regulatory Class: II
Product Code: KPI
Regulation Number: 21 CFR Part 876.5320

3. Predicate Device Information

Primary Predicate Device:

510(K) Number: K191312
Company Name: Tenscare Ltd
Trade Name: Perfect PFE
Regulatory Class: Class II
Product Code: KPI
Regulation Number: 21 CFR Part 876.5320
The predicate device has not been subject to a design-related recall.

Reference Device 1:

510(K) Number: K141643
Company Name: Internation Trade Group, Inc.
Trade Name: Yarlap
Regulatory Class: Class II
Product Code: KPI
Regulation Number: 21 CFR Part 876.5320

Reference device 2:
510(K) Number: K220161
Company Name: Shenzhen Konmed Technology Co., Ltd.
Trade Name: Biofeedback Nerve and Muscle Stimulator
Regulatory Class: Class II
Product Code: KPI
Regulation Number: 21 CFR Part 876.5320

4. Device Description

The Pelvic Muscle Trainer is a hand-held, home-use device designed to treat stress, urge and mixed urinary continence in women and maintain urinary continence in women. The device is supplied with a reusable (single-patient use) vaginal, dual-electrode, stimulation probe. The probe connects to the control unit by cable and plug and is inserted into the vagina by the end user.
Electrical stimulation is delivered via stainless steel electrodes on the probe to induce a contraction of the pelvic floor muscles. Muscle stimulation is used to train and strengthen the pelvic floor muscles in a controlled manner. Muscle stimulation is used to improve the ability of muscles to hold a contraction for an extended period of time and is a treatment for urinary incontinence. During a session, stimulation is delivered to specific muscles to encourage their contraction. The level of electrical stimulation is controlled by the end user using manual, push-button controls.
The device has 2 models, KM510 and KM516B. KM510 has 9 preset treatment programs, KM516B has 6 preset treatment programs.
The device consists of a control unit, a probe, one USB wire and one user manual.

5. Intended Use / Indications 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.

6. Test Summary

Summary of Non-clinical Performance Testing

1) Performance testing summary
The safety and performance of the Pelvic Muscle Trainer (model: KM510, KM516B) has been evaluated with the following lab bench testing:

Title of the test	Device description/sample size	Test methods/applicable standards	Acceptance criteria	Unexpected results/significant deviations	Test results
General requirements for basic safety and essential performance	The test sample is the final finished product: KM510, KM516B	IEC 60601-1: 2005/AMD1: 2012/AMD2: 2020	The test is carried out under the test method specified in the standard, and the test result is within the acceptance range of the standard.	N/A	Pass
Electromagnetic disturbances	The test sample is the final finished product: KM510, KM516B	IEC 60601-1-2: 2015/AMD1: 2020	No degradation of performance was found during test or lower than limits or measurement.	N/A	Pass

Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.	The test sample is the final finished product: KM510, KM516B	IEC 60601-1-11: 2015/AMD1: 2020	The device operates normally, and can provide basic safety and essential performance.	N/A	Pass
Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.	The test sample is the final finished product: KM510, KM516B	IEC 60601-2-10:2012 AMD 1:2016	The test is carried out under the test method specified in the standard, and the test results is within the test acceptance range of the standard.	N/A	Pass
Medicalelectrical equipment -Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems	The test sample is the final finished product: KM510, KM516B	IEC TR 60601-4-2: Edition 1.0 2016- 05	No degradation of performance was found during test or lower than limits or measurement.	N/A	Pass
IEC 62133-2 Edition1.0 2017-02 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems	The test sample is the final finished product: KM510	IEC 62133-2 Edition1.0 2017-02	The test is carried out under the test method specified in the standard, and the test result is within the acceptance range of the standard.	N/A	Pass
Battery life test	The test sample is the final finished product: KM510	N/A	The battery capacity should retain >80% initial operating time after 3 years	N/A	Pass
Output waveform testing	The test sample is the final finished product: KM510, KM516B	"Guidance Document for Powered Muscle Stimulator 510(k)s, June 9, 1999", "Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief" "IEC 60601-2-10, Particular requirements for the safety of	The output current limit r.m.s. with 500Ω resistance load is 80mA For pulse durations of less than 0.1s, the pulse energy with 500Ω resistance load shall not exceed 300mJ per pulse. The output voltage shall not exceed a peak value of 500V, when measured under open-circuit condition. Otherwise, we also set the following two Acceptance Criteria for	N/A	Pass

		nerve and muscle stimulators".	our device according to FDA Guidance. Maximum Power Density ＜ 0.25 (W/cm²)		

1) Biocompatibility testing
The vaginal probe (KM-503) is identical to the vaginal probe (KM-503) cleared in K163288. Accordingly, biocompatibility testing per requirements of the ISO 10993-1 and the FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process." from K163288 was leveraged to support biocompatibility of the subject device. This includes the testing to the following standards:

- Cytotoxicity testing per ISO 10993-5:2009/(R)2014 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- Sensitization testing per ISO 10993-10:2010/(R)2014 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- Irritation or intracutaneous reactivity testing per ISO 10993-10:2010/(R)2014 Biological evaluation of medical devices -Part 10: Tests for irritation and skin sensitization

2) Software verification and validation testing
Software verification and validation testing were conducted and documentation was provided as recommended by "Content of Premarket Submissions for Device Software Functions. Guidance for Industry and Food and Drug Administration Staff" The software for this device was considered as a "moderate" level concern, since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

3) Testing on patient leads or patient cables
The lead wire of the Konmed Incontinence Stimulation Electrode is the same lead wire use in the K220161, which complies with regulation 21 CFR 898 and IEC 60601-1: 2006:+A1: 2012+A2: 2020.

7. Comparison to predicate device and conclusion
Compared with the predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise different questions of safety or effectiveness.

Elements of Comparison	Subject Device	Primary Predicate Device (K191312)	Reference Device 1 (K141643)	Reference device 2 (K220161)	Remark
Device Name	Pelvic Muscle Trainer	Perfect PFE	Yarlap	Pelvifine Pelvic Muscle Trainer	--
510(k) Number	K260178	K191312	K141643	K220161	--
Product Code	KPI	KPI	KPI	KPI	Same
Regulation No	21 CFR Part 876.5320	21 CFR Part 876.5320	21 CFR Part 876.5320	21 CFR Part 876.5320	Same
Indications 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.	The Perfect PFE 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. The Perfect PFE is intended for OTC 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.	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.	Same

Prescriptive or OTC	OTC	OTC	Rx and OTC	OTC	Same
Number of output modes	KM510: 9 KM516B: 6	4	6	Not publicly available	Similar
Number of output channel	KM510: 1 KM516B: 1	1	2	Not publicly available	Same
Electrode Surface Area	KM510: 7.85 cm^2 KM516B: 7.85 cm^2	4.24 cm^2	6.4 cm^2	15.7 cm^2	Similar
Frequency (Hz)	KM510: 10 - 50, ±10% Stress: 12/35/50 Mixed: 10/12/20 Urge: 10/12 Tone: 35 KM516B: 10-35, ±10% Stress: 12/35 Mixed: 12/20 Urge: 10/12	Stress: 50Hz Tone: 35Hz Mixed: 10Hz/50 Hz Urge: 10Hz	10 Hz - 35Hz, program Dependent Stress: 12/35 Mixed: 12/20 Urge: 10/12	2-100Hz	Same

Pulse width (us)	KM510: 200 µS – 300 µS, ±10% Stress: 200/250/300 Mixed: 200/250/300 Urge: 200 Tone: 250 KM516B: 200 µS – 250 µS, ±10% Stress:200/250 Mixed: 200/250 Urge: 200	Stress: 300µs Tone: 250µs Mixed: 200µs / 300µs Urge: 200µs	200 µS – 250 µS, program dependent Stress: 200/250 Mixed: 200/250 Urge:200/250	50-450µs	Same
Maximum Output Voltage (V)	KM510: 40V@ 500Ω KM516B: 30V@ 500Ω	45V @ 500Ω	Not publicly available	Not publicly available	Similar
Maximum Output Current (A)	KM510: 80mA @ 500Ω KM516B: 60mA @ 500Ω	0.09A @ 500Ω	80mA +0/- 8%	94.4mA @ 500 Ω 54mA @ 2k Ω 15 mA @ 10k Ω	Similar
Maximum Phase Charge (µC)	KM510: 24 µC KM516B: 15 µC This corresponds to the longest pulse at the highest current.	24.29 @ 500Ω	80mA x 250 µS = 20 µC This corresponds to the longest pulse at the highest current.	51.4µC@500 Ω	Similar
Maximum Current Density, (mA/cm²)	KM510: 11.21 mA/ cm^2 (area=7.85 cm^2) KM516B: 8.41 mA/ cm^2 (area=7.85 cm^2)	21.2 @ 500Ω (Area=4.24 cm^2)	Not publicly available	6.01mA/ cm^2@ 500 Ω Surface = 15.7 cm^2	Similar

Maximum Average Power Density, (mW/cm²)	KM510: 14.80 mW/cm^2 @ 500Ω KM516B: 3.88 mW/ cm^2 @ 500Ω	11.6 mW/cm^2 @ 500Ω (Area=4.24 cm^2)	3.5 mW/sqcm At maximum frequency of 35Hz pulse width 200μS and current of 80mA. (P06) PC Electrode area: 6.4 cm²	0.2814mW/ cm^2@ 500 Ω	Similar
Power source	KM510: DC 3.7V/ 900mAh rechargeable lithium battery KM516B: DC 3.0V 2×AAA batteries	2 Alkaline AA 1.5V Batteries	Not publicly available	7.4V DC/1200mAh rechargeable lithium battery	Similar
Electrode lead wires and patient cable compliance with 21 CFR 898	Yes	Yes	Not publicly available	Not publicly available	Same

The below tables compare the subject device treatment programs to the predicate and reference devices.

KM510:

Utility	KM510 Max. 80mA	K141643 Max. 80mA	K191312 Max. 90mA	Rate (Hz)	Pulse Duration(μs)	work (s)	rest (s)	Time (min)
Mixed	P01			12	200	5	5	15
		1		12	200	5	5	15
Mixed	P02			20	250	8	8	20
		2		20	250	8	8	20
Mixed	P03.1			10	200	6	12	10
			mixed	10	200	/	/	20
	P03.2			50	300	5	15	10
			mixed	50	300	/	/	20
Urge	P04			12	200	5	10	15
		3		12	200	5	10	15
Urge	P05			10	200	6	12	20
		4		10	200	6	12	20
Stress	P06			12	250	5	15	15
		5		12	250	5	15	15
Stress	P07			35	200	6	18	20
		6		35	200	6	18	20
Stress	P08			50	300	5	15	15
			stress	50	300	6	10	20
Tone	P09			35	250	5	5	20
			tone	35	250	5	6	20

KM516B:

Utility	KM516B Max. 60mA	K141643 Max. 80mA	Rate (Hz)	Pulse Duration(μs)	Work (s)	Rest (s)	Phase Time(min)

Mixed	P01		12	200	5	5	15
		1	12	200	5	5	15
	P02		20	250	8	8	20
		2	20	250	8	8	20
Urge	P03		12	200	5	10	15
		3	12	200	5	10	15
	P04		10	200	6	12	20
		4	10	200	6	12	20
Stress	P05		12	250	5	15	15
		5	12	250	5	15	15
	P06		35	200	6	18	20
		6	35	200	6	18	20

The main differences between the subject and predicate device are the stimulation parameters (maximum current density and maximum average power density) and the power source. These differences were addressed with selection of reference devices and the testing summarized above.

Final Conclusion:

The performance testing provided support a substantial equivalence determination. The subject device Pelvic Muscle Trainer (model: KM510, KM516B) is substantially equivalent to the predicate device.