May 6, 2026

Shenzhen Changkun Technology Co., Ltd.
% Reanny Wang
Manager
Shenzhen Reanny Medical Devices Mgmt Consulting Co., Ltd
Rm 1509, Jingting Building, Dongzhou Community, Guangming St
Shenzhen, Guangdong 818000
CHINA

Re: K252552
Trade/Device Name: Pelvic Floor Rehabilitation Therapy Device (PD2301/PD2302/PD2303)
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: II
Product Code: KPI
Dated: April 3, 2026
Received: April 3, 2026

Dear Reanny 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 (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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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.	K252552

Please provide the device trade name(s).

Pelvic Floor Rehabilitation Therapy Device (PD2301/PD2302/PD2303)

Please provide your Indications for Use below.

Pelvic Floor Rehabilitation Therapy Device is intended to provide electrical stimulation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress and urge urinary incontinence in women.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

I. SUBMITTER

Shenzhen Changkun Technology Co., Ltd.

Room 101, Building 1, 15 Xiusheng 2nd Road, Xiuxin Community, Kengzi Subdistrict, Pingshan District, Shenzhen City, Guangdong Province, China

Phone Number: + 86 (755) 273-91220

Contact Person: Wang Qingpeng

Date Prepared: May 5, 2026

II. DEVICE

Name of Device: Pelvic Floor Rehabilitation Therapy Device (PD2301,PD2302,PD2303)

Common Name: Nonimplanted electrical continence device

Model(s): PD2301,PD2302,PD2303

Regulation Name: Nonimplanted electrical continence device

Regulatory Class: II

Product Code: KPI

Regulation Number:21 CFR 876.5320

III. PREDICATE and REFERENCE DEVICES

Predicate device:

Manufacturer	Predicate Device	510(k) Number	Approval Date
International Trade Group, Inc.	Yarlap	K141643	April 24, 2015

Reference device I:

Manufacturer	Predicate Device	510(k) Number	Approval Date
Shenzhen Konmed Technology Co., Ltd.	Pelvifine Pelvic Muscle Trainer	K163288	January 18, 2018

Reference device II:

Manufacturer	Predicate Device	510(k) Number	Approval Date
InMode Ltd	InMode System with vTone Applicator	K200293	May 5, 2020

These predicate and Reference devices have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

Pelvic Floor Rehabilitation Therapy Device is an over-the-counter, non-implantable, home use pelvic floor muscle stimulator device for the treatment of stress and urge urinary incontinence based on electrical stimulation.

The device contains one reusable (single-patient use) vaginal electrode, a main electrical stimulator unit, and a user manual. The main unit is made out of ABS plastic, and the vaginal probe is made out of ABS plastic and stainless steel. When working, it is powered by the internal lithium battery. After the power is exhausted, it is charged by the external power charger. The device cannot work when charging. The device has 4 modes: 1) P1 for mild stress urinary incontinence, 2) P2 for moderate stress urinary incontinence, 3) P3 for mild urge urinary incontinence, and 4) P4 for moderate urge urinary incontinence. The treatment program and stimulation intensity can be selected by the user by pressing the buttons on the main unit. An LCD display shows the current program and intensity level. The duration of each treatment program is fixed and cannot be adjusted by the user. At the end of a treatment session, the device automatically shuts down.

There are a total of three models of Pelvic Floor Rehabilitation Therapy Device: PD2301, PD2302 and PD2303. Its product principle, structural composition, intended use, key components, electrical structure, etc. are exactly the same. There are differences in appearance and number of buttons.

The core principle of the device is to activate and exercise the muscle through electrical stimulation. The device sends a low-frequency pulse current through electrode to the muscle causing the muscle to contract and relax, and enhance the strength and endurance of pelvic floor muscles, thereby help with the management of stress and urge urinary incontinence.

V. Indications for Use

Pelvic Floor Rehabilitation Therapy Device is intended to provide electrical stimulation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress and urge urinary incontinence in women.

VI. Comparison of Technological Characteristics

The Pelvic Floor Rehabilitation Therapy Device has a similar intended use and operational characteristics as the predicate device and reference device. The reference devices were used to support the stimulation parameters for P1 and P4 and the output intensity levels. Any differences between the subject device and the listed predicate device and reference device do not raise different questions of safety or effectiveness and are addressed with non-clinical testing.

Device	Subject device	Predicate Device	Reference device	Reference device II

	K252552	K141643	K163288	K200293
Manufacturer	Shenzhen Changkun Technology Co., Ltd.	International Trade Group, Inc.	Shenzhen Konmed Technology Co., Ltd.	InMode Ltd.
Product name	Pelvic Floor Rehabilitation Therapy Device	Yarlap	Pelvifine Pelvic Muscle Trainer	InMode System with vTone Applicator
Indications for Use (IFU)	Pelvic Floor Rehabilitation Therapy Device is intended to provide electrical stimulation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress and urge urinary incontinence 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.	Pelvifine Pelvic Muscle Trainer (Model: KM518) is a non-implanted muscle stimulator designed to treat stress, urge and/or mixed urinary incontinence in women. It applies stimulation to the pelvic floor muscles and surrounding structures to improve strength and support.	The InMode System with the vTone Applicator 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
Intended Papulation	Women with stress and urge urinary incontinence	Women with stress, urge and mixed urinary incontinence	Women with stress, urge and mixed urinary incontinence	Women with stress, urge and mixed urinary incontinence
Prescription or OTC	OTC	Prescription Use & OTC	OTC	Prescription Use
Use Environment	Home Environment	Home Environment	Home Environment	Professional healthcare facility
Mechanism of Action	Muscle contraction by electrical stimulation	Muscle contraction by electrical stimulation	Muscle contraction by electrical stimulation	Muscle contraction by electrical stimulation
Dimensions	Main Unit (H*W*D) PD2301:147mmx52mmx33mm PD2302:148mm*47mm*37mm PD2303:130mmx68mmx20mm Vaginal Electrode	Main Unit: 108 X 62 X 23 mm	Main Unit: 150mm x 73mm x 20mm Probe: 145mm x 25mm x 25mm	Console: 35cm W x 35cm D x 100cm H Applicator: 8.8cm L x 2.8cm D

	93.3mm*29.1mm			
Power source	Internal lithium battery, rechargeable. DC3.7V, Not replaceable by user.	1 X 9 Volt Alkaline Battery (standard 800mAh)	9Vdc Battery	Main Line Frequency (nominal) 50/60 Hz Input Voltage (nominal) 100-240V AC Input Current (rms) 2A
Output Intensity Level	50	---	100	50
Timer Range (min)	25 mins	15~20mins	15~20 minutes	Up to 60 mins
Housing Materials and Construction	Main unit: ABS plastic Probe Material: ABS plastic, Stainless steel	Main unit: ABS plastic Probe Material: ABS plastic, Stainless steel	Main unit: ABS plastic Probe Material: ABS plastic, Stainless steel	---
Output Waveform	Biphasic, Symmetrical	Biphasic, Symmetrical	Biphasic	Biphasic
Pulse Shape	Rectangular	---	Rectangular	Rectangular
Maximum Output Voltage (±10%）	45V @500Ω 50V @2 kΩ 52V @10kΩ	40V @500Ω 100V @2 kΩ 190V @10kΩ	37Vdc @500Ω	45V @500Ω 54V @2 kΩ 54V @10kΩ
Maximum Output Current (±10%）	90mA@500Ω 25mA@2KΩ 5.2mA@10KΩ	80mA@500Ω 50mA@2kΩ 19mA@10kΩ	<80mA @500Ω	90mA@500Ω current limit 28mA@2kΩ 5.6mA@10kΩ
Pulse Frequency (Hz)	10/30/35Hz	10 ~ 35Hz	10~40Hz	3 ~100 Hz
Pulse Width (μsec.)	100/120 μs	200 ~ 250μS	150/ 200/220 μs	50 ~ 450 μs
Net Charge @ 500 Ω [μC/pulse]	0 μC	0 μC	0 μC	0 μC
Maximum Phase	10.8μC @500Ω	20μC @500Ω	19.8μC @500Ω	40.5 μC @ 500Ω

Charge [μC]				
Maximum Current Density (mA/cm^2, 500Ω)	8.9 mA/cm^2	12.5 mA//cm^2	9.48 mA/cm^2	9.4 mA/cm2
Maximum Average Power Density [mW/cm^2] (using smallest electrode conductive surface area)	2.81 mW/cm^2	3.5 mW /cm^2	3.09 mW /cm^2	33.8 mW /cm2
Electrode Surface Area	10.1 cm^2 (x2)	6.4 cm^2 (x2)	7.85cm^2 (x2)	9.58 cm2(x2)
Lenth of probe	9.3cm(Excluding the joint)	3.5 inch(8.89cm)	---	---
Width of probe	2.9cm	1 inch (2.54cm)	---	---
Suggested penetration depth of probe	6cm	---	5.5cm	---
On Time (sec.)	7/9s	5/6s	4/5/6s	1-60 sec
Off Time (sec.)	5/10s	10/12/15/18s	4/5/12/15s	1-60 sec

VII. Summary of Non-Clinical Performance Testing

Below is a list of the tests that were performed and successfully completed for the subject device per the specified guidance and standards:

- Biocompatibility testing according to ISO 10993-1:2018 - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process and FDA Guidance “Use of International Standard ISO 10993-1” (2016).
- Electrical Safety testing according to IEC 60601‑1: 2005+A1:2012+A2:2020 - Medical electrical equipment – Basic safety and essential performance
- Battery safety testing according to IEC 62133-2: 2017 - 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 and UN 38.3 Testing for Lithium Batteries

- Electromagnetic Compatibility testing according to IEC 60601‑1-2: 2014+AMD1:2020 - General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests
- Software Verification and Validation Testing according to FDA's Guidance " Content of Premarket Submissions for Device Software Functions"
- Performance test according to IEC 60601-2-10:2012, Medical electrical equipment -- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- Electrical performance testing to verify the stimulation parameters
- Use life testing to support the service life of the main unit and the vaginal electrode

All pre-determined acceptance criteria were met.

VIII. Conclusions

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device Pelvic Floor Rehabilitation Therapy Device is as safe and effective as the predicate device. The subject device and the predicate device have the same intended use/indications for use and similar technological characteristics. The differences between the subject device and the predicate device do not affect the principles of operation, underlying technology, overall electrical stimulation parameters and principal functionality. The differences between the subject device and the predicate device do not present different questions of safety or effectiveness and the performance tests conducted on the subject device support the device is as safe and effective as the predicate device. The reference devices adequately supported the stimulation parameters for P1 and P4 and the output intensity levels.