January 18, 2018

Shenzhen Konmed Technology Co., Ltd.
% Cassie Lee
Guangzhou Glomed Biological Technology Co., Ltd.
Suite 306, Kecheng Mansion, No.121 Science Road
Guangzhou Science Park
Guangzhou, 510663 CN

Re: K163288
Trade/Device Name: Pelvifine Pelvic Muscle Trainer
Regulation Number: 21 CFR§ 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: II
Product Code: KPI
Dated: December 19, 2017
Received: January 16, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163288

Device Name
Pelvifine Pelvic Muscle Trainer, Model: KM518

Indications for Use *(Describe)*
The 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.

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.

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Chapter 5. 510(k) Summary

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

510(k) Owner's Name: Shenzhen Konmed Technology Co., Ltd.
Establishment Registration Number: Applying
Address: 703B, Haide building A, Nanxin Road, Nanshan, Shenzhen, China
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Contact Person: Tony (Manager)
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Application Correspondent:
Contact Person: Ms. Cassie Lee
Guangzhou GLOMED Biological Technology Co., Ltd.
Address: Suite 306, Kecheng Mansion, No.121 Science Road, Guangzhou Science Park, Guangzhou 510663, China
Tel: +86-20-61099984
Email: regulatory@glomed-info.com

2. Subject Device Information

Trade Name:	Pelvifine Pelvic Muscle Trainer
Common Name:	Pelvic Floor Muscle Stimulator
Classification name:	Stimulator, Electrical, Non-Implanted for Incontinence
Review Panel:	Gastroenterology/Urology
Product Code:	KPI
Regulation Class:	II
Regulation Number:	21 CFR 876.5320

3. Predicate Device Information

Sponsor	InControl Medical, LLC	International Trade Group, Incorporated	InControl Medical, LLC
Device Name and Model	InTone	YARLAP	ApexM
510(k) Number	K110179	K141643	K150183

Product Code	KPI	KPI	KPI
Regulation Number	21 CFR 876.5320	21 CFR 876.5320	21 CFR 876.5320
Regulation Class	II	II	II

2. Device Description

The Pelvifine Pelvic Muscle Trainer is a product designed to give women the opportunity to strengthen their pelvic floor muscles.

This device is a dual-channel stimulator combining several treatment programs into one unit. Channel B is for the Junior User (who use the device no more than 5 times) and Channel A is for the Senior User (who use the device more than 5 times). It offers full control of Pulse Widths, Rates, Ramp up times, and Work/Rest cycles.

5. Intended Use / Indications for Use

The 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.

6. Test Summary

The Pelvifine Pelvic Muscle Trainer (Model: KM518) has been evaluated the safety and performance by lab bench testing and usability testing as following:

- Electrical safety test according to IEC 60601-1 and IEC 60601-2-10 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- Biocompatibility test according to ISO 10993-5 and ISO 10993-10 standards
- Usability test according to IEC 62366 standard
- 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 characterize the output specifications of the device according to Guidance for Transcutaneous Electrical Nerve Stimulator for Pain Relief Intended for Over the Counter Use and Guidance for Powered Muscle Stimulator for Muscle Conditioning

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of subject device is substantially to the predicate devices identified above.

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	**Subject Device**	**Predicate Device Equivalent**			**Remark**
Device Name and	Pelvic Muscle Trainer,	InTone	YARLAP	ApexM	--

Sponsor: *Shenzhen Konmed Technology Co., Ltd.*
Subject Device: *Pelvic Muscle Trainer, Model: KM518*
Document Name: *510(k) Summary*

Elements of Comparison		**Subject Device**	**Predicate Device Equivalent**			**Remark**
Model		Model: KM518				
510(k) Number		K163288	K110179	K141643	K150183	--
Intended Use & Indications for Use		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 InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: strengthening of pelvic floor muscles and inhibition of the dletrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.	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.	ApexM 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.	SE Note: Identical to ApexM
Power Source(s)		9Vdc Battery	4/5 AA nickel metal hydride battery	--	4 x AAA Alkaline battery	SE Note1
Method of Line Current Isolation		Type BF Applied Part	Type BF Applied Part	Type BF Applied Part	Type BF Applied Part	SE
Patient Leakage Current	NC	< 100 μA	N/A (battery)	--	N/A (battery)	SE Note 1
	SFC	< 500 μA	N/A (battery)	--	N/A (battery)	
Number of Output Channels		2 (only the selected one channel will work during operation)	1	--	1	SE Note 2
Number of Output Modes		12	1	--	1	SE Note 2
Output Intensity Level		100	--	--	--	SE Note 2
Timer Range		15~20 minutes	12 minutes	--	10~15 minutes	SE Note 2
Weight		Main Unit: 300g Probe: 200g	--	--	--	SE Note 2
Dimensions		Main Unit: 150mm x 73mm x 20mm Probe: 145mm x 25mm x	Insertion Unit: 12.2” x 2.5” x 4.0” Inflatable Probe: 5.5” x 2.2” x 2.5”	--	Insertion Unit : 12.2”x 2.5”x 4.0” Inflatable Probe: 5.5”x 2.2”x 2.5”	SE Note 2

Elements of Comparison	**Subject Device**	**Predicate Device Equivalent**			**Remark**
	25mm				
Electrode Surface Area	7.85cm^2 (x 2)	10.5cm^2 (x 2)	6.4cm^2 (x 2)	6.00cm^2 ± 0.5cm^2 (x 2)	SE Note 3
Housing Materials and Construction	Main unit: ABS plastic Probe Material: ABS plastic, Stainless steel	ABS plastics	--	Main unit: ABS plastic Insertion Material: Silicone, Plastics	SE Note 4
Waveform and Shape	Rectangular pulses, Biphasic	Rectangular pulses, Biphasic	Rectangular pulses, Biphasic	Rectangular pulses, Monophasic	SE Note: Identical to InTone
Maximum Output Voltage	37Vdc @500Ω	50Vdc @500Ω	--	40Vdc @500Ω	SE Note 3
Maximum Output Current	<80 mA @500Ω	100mA @500Ω	80mA±10% @ 500Ω 50mA±10% @ 2kΩ 19mA±10% @10kΩ	80mA @500Ω	SE Note 3
Pulse Duration	150μs, 200μs, 220μs	200μs	200~250μs	200μs	SE Note 3
Pulse frequency	10~40Hz	50Hz	10~35Hz	13, 50Hz	SE Note 3
Net Charge (per pulse)	0 μC @ 500Ω	--	0μC @ 500Ω	--	SE Note 3
Maximum Phase Charge	19.8 μC @ 500Ω	20μC @ 500Ω	20μC @ 500Ω	16μC @ 500Ω	SE Note 3
Maximum Current Density	9.48 mA/cm²	4.7 mA/cm^2	12.5mA/cm^2 (Vaginal)	13.3 mA/cm^2	SE Note 3
Maximum Average Power Density	3.09 mW/cm^2	4.8 mW/cm^2	3.5 mW/cm^2	5.33 mW/cm^2	SE Note 3
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	SE
Electrical Safety	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE

Supplement SE table for identifying the specific urinary incontinence type											
Utility	Predicate device K141643	Subject device	Rate Hz	Pulse us	Work Sec.	Rest Sec.	Time Min.*	Max. W/cm^2 80mA	Ave. W/cm^2 30mA	Ave. W/cm^2 45mA	maximum phase charge

Mixed	Mode 1	--	12	200	5	5	15	1.2	0.17	0.38	20 C @ 500Ω
Mixed	Mode 2	--	20	250	8	8	20	2.5	0.35	0.79	20 C @ 500Ω
Mixed	--	P04	10	220	5	5	20	1.1	0.31	0.47	19.8 C @ 500Ω
Mixed	--	P05	10	220	5	5	20	1.1	0.31	0.47	19.8 C @ 500Ω
Mixed	--	P06_1	10	220	4	4	20	1.02	0.31	0.47	19.8 C @ 500Ω
Mixed	--	P06_2	20	220	4	4		1.2	0.63	0.94	19.8 C @ 500Ω
Mixed	--	P07_1	20	220	5	5	20	1.2	0.63	0.94	19.8 C @ 500Ω
Mixed	--	P07_2	20	220	5	5		1.2	0.63	0.94	19.8 C @ 500Ω
Mixed	--	P07_3	20	220	5	5		1.2	0.63	0.94	19.8 C @ 500Ω
Mixed	--	P07_4	10	220	4	4		1.2	0.32	0.47	19.8 C @ 500Ω
Mixed	--	P08	20	220	5	5	20	1.2	0.63	0.94	19.8 C @ 500Ω
Urge	Mode 3	--	12	200	5	10	15	1.2	0.17	0.38	20 C @ 500Ω
Urge	Mode 4	--	10	200	6	12	20	1.0	0.14	0.32	20 C @ 500Ω
Urge	--	P03	10	200	6	12	15	0.9	0.28	0.42	19.8 C @ 500Ω
Stress	Mode 5	--	12	250	5	15	15	1.5	0.21	0.47	20 C @ 500Ω
Stress	Mode 6	--	35	200	6	18	20	3.5	0.5	1.11	20 C @ 500Ω
Stress	--	P01	40	220	6	15	20	2.3	1.23	1.87	19.8 C @ 500Ω
Stress	--	P02	10	220	5	15	20	1	0.31	0.46	19.8 C @ 500Ω

* The treatment times listed for the subject device are for Channel A. Channel B has a 3-minute treatment time.

Comparison in Detail(s):

Note 1:

Although the “Power Source(s)”, “Patient Leakage Current”, “Weight”, and “Dimensions”, a little different from the predicate devices, the differences will not raise any safety or effectiveness issue.

Note 2:

Although the “Number of Output Modes” “Output Intensity Level”, “Timer Range”, “Weight” and “Dimensions” of subject device are different from the predicate devices, the differences will not raise any safety or effectiveness issue.

Note 3:

Although the “Electrode Surface Area”, “Maximum Output Voltage”, “Maximum Output Current”, “Pulse Duration”, “Pulse Frequency”, “Net Charge (per pulse)”, “Maximum Phase Charge”, “Maximum Current Density”, “Maximum Average Power Density” are a little different from the predicate devices, the differences will not raise any safety or effectiveness issue.

Note 4:

Although the “Housing Materials and Construction” are a little different from the predicate devices, the differences will not raise any safety or effectiveness issue.

Note 5:

The stimulation parameters for “specific urinary incontinence type” of subject device and predicate device are very similar , so the differences will not significantly impact safety and effectiveness.

Finial Conclusion:

The subject device “Pelvifine Pelvic Muscle Trainer” is Substantial Equivalent to the predicate devices.

8. Date of the summary prepared: December 19, 2017