September 21, 2023

Nanjing Vishee Medical Technology Co., Ltd.
Lisa Tan
Regulatory Affairs
Building 9, No.19, Ningshuang Road, Yuhuatai District
Nanjing, Jiangsu 210012
China

Re: K230767
Trade/Device Name: Pelvic Floor Muscle Stimulator
Regulation Number: 21 CFR§ 876.5320
Regulation Name: Non-Implanted Electrical Continence Device
Regulatory Class: II
Product Code: KPI
Dated: August 17, 2023
Received: August 21, 2023

Dear Lisa Tan:

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,

Angel A. Soler-garcia -S

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)*
K230767

Device Name
Pelvic Floor Muscle Stimulator

Indications for Use *(Describe)*
Pelvic Floor Muscle Stimulator (Model name: MagBelle AF180) is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of male and female urinary incontinence.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 (k) Summary

1. Submitter Information

510 (k) submitter:	Nanjing Vishee Medical Technology Co., Ltd.
Address:	Building 9, No.19, Ningshuang Road, Yuhuatai District, Nanjing, Jiangsu 210012, China
Applicant Contact Person:	Mr. Kai Qiu Phone: +86 025696708 Email : qiukai@vishee.com
Correspondent Contact:	Mrs. Lisa Tan Phone: +86 19850817942 Email : tanyumei@vishee.com
Preparation date:	September 12, 2023

2. Device Name

Trade Name of the Device:	Pelvic Floor Muscle Stimulator
Common Name:	Nonimplanted electrical continence device
Classification Name:	Non-Implanted Electrical Continence Device
Classification Regulation:	21 CFR 876.5320
Device Class:	II
Panel:	Gastroenterology/Urology
Product Code:	KPI

3. Predicate and Reference Devices

	510(k) Number	Trade Name of the Device
Predicate:	K181497	HPM-6000UF
Reference:	K201014	MyOnyx System

The predicate device was never subjected to a design related recall.

4. Device Description

The Pelvic Floor Muscle Stimulator (model: MagBelle AF180) is a non-invasive therapeutic device which produces electromagnetic field that interacts with the tissues in the pelvic region of the human body. The electromagnetic field delivered in the muscular tissue area triggers the muscle stimulation.

MagBelle AF180 consists of the main unit and the chair applicator. The MagBelle AF180 is equipped

with a color touch screen that facilitates the use of the device. The on-screen information guides the user step-by-step through the entire therapy procedure. The therapeutic parameters can also be set using the touch screen, buttons and knob on the device. During the therapy, the device keeps information about the applied therapy type, remaining therapy time and main therapy parameters on the screen. The subject device should only be used under the continued supervision of a physician or licensed practitioner. The device supports 3 different function modes: Magnetic stimulation function, Kegel biofeedback training function and Triggering magnetic stimulation function (combination of Magnetic stimulation function and Kegel biofeedback training function).

5. Indications For Use

Pelvic Floor Muscle Stimulator (Model name: MagBelle AF180) is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of male and female urinary incontinence.

6. Comparison of the Technological Characteristics with Predicate and Reference Devices:

Device & Predicate Device(s):	K230767 (Subject Device)	K181497 (Predicate Device)	K201014 (Reference Device)
Device Name	Pelvic Floor Muscle Stimulator	HPM-6000UF	MyOnyx System
Indication for Use	Pelvic Floor Muscle Stimulator (model: MagBelle AF180) is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of male and female urinary incontinence.	HPM-6000UF is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of male and female urinary incontinence.	The MyOnyx System is indicated for acute and ongoing treatment of stress, urge, or mixed urinary incontinence, where urinary control may be improved through electrical stimulation that strengthens the pelvic floor muscles or inhibits the detrusor muscle through reflexive mechanisms. The system also uses EMG-based or pressure-based biofeedback to help control and strengthen the pelvic floor muscles in the treatment of urinary incontinence.
Function	Pelvic floor muscle stimulation	Pelvic floor muscle stimulation	Pelvic floor muscle stimulation
Prescription Use Only	Yes	Yes	Yes
Type of energy	Magnetic field	Magnetic field	Electrical
Power source	100-240 V AC, 50-60 Hz, max 12 A	100-240 V AC, 50-60 Hz, max 14 A	Max 140mA @ 5Vdc (700mW)
Therapy Process	Specific therapy mode is selected by the clinician based on the patient's symptoms.	Specific therapy mode is selected by the clinician based on the patient's symptoms.	Specific therapy mode is selected by the clinician based on the patient's symptoms
Kegel Exercise Mode	Present	Absent	Present
Applicator	Chair	Chair	Vaginal and Anal probes

Stimulation source	Magnetic coil	Magnetic coil	Current
Magnetic field strength	0.7-2.5 T	0.7-2.5 T	Not Applicable
Pulse repetition rate	1-150 Hz	1-150 Hz	5-80 Hz
Pulse width	340μs (±20μs)	280 μs (±20%)	150-400 μs
Variation of Pulse intensity (dB/dt)	Up to 24 mT/ μs±20%	Up to 28 mT/ μs±20%	Not Applicable
Pulse amplitude adjustment	0-100%	0-100%	Not Applicable
Pulse shape	Sine, biphasic	Sine, biphasic	Symmetrical, rectangular, bipolar, biphasic
Interface	Touch screen	Touch screen	LCD
Firmware controlled	Yes	Yes	Yes
Applicator dimensions (WxHxD)	28x48x28 in.	29x29x29 in.	28 mm diameter (Vaginal Probe) and 19.6 mm diameter (Anal probe)
Treatment Environment	Hospital/Clinics only	Hospital/Clinics only	Under medical supervision only

As evidenced by the above table, both the subject and the predicate devices have similar intended use, but the subject and predicate devices have different technological characteristics. However, performance testing was conducted on the subject device, and it was established that the differences in technological characteristics between the subject and the predicate does not raise different questions of safety or effectiveness.

7. Non-Clinical Testing

Below is a list of the tests that were performed and successfully completed for the subject device per the below 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: 2020 - *Medical electrical equipment – Basic safety and essential performance*

- Electromagnetic Compatibility testing according to IEC 60601-1-2: 2020 - *General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests*

- IEC 60601-2-10:2016 – *Particular requirements for the basic safety and essential performance of nerve and muscle stimulators*

- Software Verification and Validation Testing according to FDA's Guidance "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*"

Additionally, performance bench data was submitted for device performance and durability of the subject device. This data included:

- o Service life verification test
- o Stimulation Coil Surface Temperature Rise Test
- o Maximum Magnetic Field Strength Test
- o Cybersecurity testing

All pre-determined acceptance criteria were met.

8. Clinical Data Summary

To verify the Kegel Biofeedback functionality, the sponsor tested the subject device in 100 urinary incontinence patients (male and female, age range: 22-70) in a hospital set-up. All the patients' pelvic floor muscles strength was tested manually by a clinician by using modified Oxford Grading Scale. Then, the patients' pelvic floor muscle strength was measured by using the subject device. Thus, the Kegel biofeedback mode of the subject device was calibrated to identify the values of the biofeedback signal corresponding to normal and weak pelvic floor muscle strength. The pelvic floor muscle strength measured by the subject device was also compared to the pelvic floor muscle strength measured by a reference device, K201014 (MyOnyx System). Pelvic floor muscle conditions evaluated by both the subject and the reference devices were found to be comparable to each other.

9. Conclusions

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