April 27, 2026

Hunan Accurate Bio-Medical Technology Co., Ltd.
Yanhong Mo
Regulatory Engineer
Accurate Industrial Park, No.108, Zhixian Rd.
Xuelian Community, Xueshi Street of Yuelu District
Changsha, Hunan 410208
CHINA

Re: K252748
Trade/Device Name: Pelvic Floor Exerciser (PF01)
Regulation Number: 21 CFR 884.1425
Regulation Name: Perineometer
Regulatory Class: II
Product Code: HIR
Dated: August 29, 2025
Received: March 30, 2026

Dear Yanhong Mo:

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,

Negeen Haghighi -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)*
K252748

Device Name
Pelvic Floor Exerciser (PF01)

Indications for Use *(Describe)*

The Pelvic Floor Exerciser is a perineometer designed to treat stress, mild-moderate urge and mixed urinary incontinence in women, by strengthening of the pelvic floor muscles through exercise. This device provides biofeedback via smart phone technology.

Pelvic Floor Exerciser is indicated for an adult female.

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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K252748
510(K) SUMMARY

1. SUBMITTER INFORMATION

510(k) Submitter:	Hunan Accurate Bio-Medical Technology Co., Ltd.
Address:	Accurate Industrial Park, No. 108, Zhixian Road, Xuelian Community, Xueshi Street of Yuelu District, Changsha, Hunan 410208, China
Applicant Contact Person:	Mr. Li Zhang, General Manager Phone: +86 731-8559853 E-Mail: regulation@accbiomed.com
Correspondent Contact:	Mrs. Yanhong Mo, Regulatory Engineer Hunan Accurate Bio-Medical Technology Co., Ltd. Accurate Industrial Park, No. 108, Zhixian Road, Xuelian Community, Xueshi Street of Yuelu District, Changsha, Hunan 410208, China Phone : +86 18682041674 E-Mail : regulation@accbiomed.com.
Date Summary Prepared:	April 22, 2026

2. DEVICE NAME

Trade Name of the Device:	Pelvic Floor Exerciser (PF01)
Common Name:	Perineometer
Classification Name:	Perineometer
Classification Regulation:	21 CFR 884.1425
Device Class:	Class II
Panel	Gastroenterology/Urology
Product Code	HIR

3. PREDICATE DEVICE

Predicate Devices:	Perifit Care+
510(k) number	K231780
Company Name	X6 Innovations

The predicate device has not been subject to a design related recall.

4. DEVICE DESCRIPTION

The Pelvic Floor Exerciser (PF01) device consists of a vaginal probe covered in a silicone sheath that is temporarily inserted into the vagina. Sensors located under the silicone sheath measure the strength of contraction of the user's pelvic floor muscles. This information is then transmitted wirelessly to a smartphone application in order to provide real-time visual feedback to the user regarding muscle contraction strength during pelvic floor muscle exercise. The smartphone application includes special games that are based on Kegel exercise principles. It is a single-patient, reusable device supplied over the counter.

5. INDICATION FOR USE

The Pelvic Floor Exerciser is a perineometer designed to treat stress, mild-moderate urge and mixed urinary incontinence in women, by strengthening of the pelvic floor muscles through exercise. This device provides biofeedback via smart phone technology.

Pelvic Floor Exerciser is indicated for an adult female.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

Technical Characteristics	Subject Device: Pelvic Floor Exerciser (PF01) (K252748)	Predicate Device: Perifit care + (K231780)
Indication For Use	The Pelvic Floor Exerciser is a perineometer designed to treat stress, mild-moderate urge and mixed urinary incontinence in women, by strengthening of the pelvic floor muscles through exercise. This device provides biofeedback via smart phone technology. Pelvic Floor Exerciser is indicated for an adult female.	Perifit Care+ is a perineometer designed to treat stress, mild-moderate urge and mixed urinary incontinence in women, by strengthening of the pelvic floor muscles through exercise. This device provides biofeedback via smart phone technology. Perifit Care+ is indicated for an adult female.
Mode of Use	Reusable for single patient	Reusable for single patient
Principle of Operation	A probe inserted into the vagina to determine the strength of the pelvic floor muscles. Probe sends signals to external device to indicate muscle contraction strength to encourage and assist user with voluntary Kegel exercises.	A probe inserted into the vagina to determine the strength of the pelvic floor muscles. Probe sends signals to external device to indicate muscle contraction strength to encourage and assist user with voluntary Kegel exercises.
Sensing method	Output from force sensing resistors (wireless).	Output from force sensing resistors (wireless).
Sensor's placement	Inside the rigid plastic enclosure	Inside the rigid plastic enclosure
Materials	Rigid plastic (PC/ABS) structure enclosed within a medical grade silicone outer layer	Rigid plastic (PC/ABS) structure enclosed within a medical grade silicone outer layer
Parameter monitored	Analogue to digital output of uncalibrated force exerted against external walls of device by pubococcygeus and puborectalis muscles.	Analogue to digital output of uncalibrated force exerted against external walls of device by pubococcygeus and puborectalis muscles.
Motion Sensor	Present	Present
User Interface	Smartphone GUI	Smartphone GUI
Anatomical Sites	Female Pubococcygeus muscle area	Female Pubococcygeus muscle area
External shape	Two egg shaped sensing areas	Two egg shaped sensing areas
Shaft length	88.5 mm	87.5 mm
Weight	42g	40g
Power Source	Non-rechargeable batteries Voltage 3.0VDC	Non-rechargeable batteries Voltage 3.0VDC

As shown in the table above, the subject and predicate devices have similar intended use and technological characteristics. Performance testing was conducted on the subject device to establish its safety and effectiveness.

7. NON-CLINICAL TESTING

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

- Biocompatibility Testing in accordance with FDA Guidance: *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process*

- Electrical Safety testing according to IEC 60601-1: 2020 - *Medical electrical equipment – Basic safety and essential performance* and IEC 60601-1-11:2020 -*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*

- 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* and IEC 60601-4-2:2024-*Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic compatibility – Test plan and test report*

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

- Cybersecurity Verification and Validation Testing according to FDA's Guidance: *Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions*

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

- Probe Tail Tensile Strength Testing
- Probe Tail Excessive Bending Testing
- Cleaning Validation Testing
- Sensor Accuracy and Range Testing
- Bluetooth Signal Strength And Connection Stability Testing
- Dimensional Verification Testing
- Vibration and Drop Testing
- Service Life Verification Testing Including Battery Consumption Test

All pre-determined acceptance criteria were met.

8. CONCLUSION

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