December 20, 2023

X6 Innovations
% Lina Kontos
Partner
Hogan Lovells US LLP
555 13th Street NW
Washington, DC 20004

Re: K231780
Trade/Device Name: Perifit Care+
Regulation Number: 21 CFR§ 884.1425
Regulation Name: Perineometer
Regulatory Class: II
Product Code: HIR
Dated: November 21, 2023
Received: November 21, 2023

Dear Lina Kontos:

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: 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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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,
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OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
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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)*

K231780

Device Name

Perifit Care+

Indications for Use *(Describe)*

The 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.

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.

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510(k) SUMMARY

X6 Innovations' Perifit Care+

Submitter

X6 Innovations
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75008 Paris, France
Phone: +33 6 51 66 55 94
Contact Person: Robin Reynaud Date
Prepared: December 19, 2023

Date of Submission: June 16, 2023

Name of Device: Perifit Care+

Common or Usual Name: Perineometer

Classification Name: (21 CFR 884.1425) Perineometer

Regulatory Class: Class II

Product Code: HIR

Predicate Devices:

Perifit (K221476)

Intended Use / Indications for Use

The 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.

Device Description

The Perifit Care+ device consists of a rigid probe covered in a silicone sheath that is temporarily inserted into the vagina. Sensors located under the 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 feedback to the user. It is a single patient, reusable device to be supplied over-the-counter.

Comparison of Technological Characteristics

Pelvic floor muscle contraction force detection and instantaneous feedback to the user's smartphone is the technological principle for both the subject and predicate devices. An intravaginal device with embedded force sensors is used to monitor the contraction force of the user's pelvic floor muscles.

This information is transmitted to the patient's smartphone via bluetooth and is displayed on the screen. The subject and predicate devices are based on the following same technological elements:

- an intravaginal probe with external silicone shell
- force sensors and bluetooth transmitter embedded inside the probe
- a smartphone with a dedicated App

The technological differences between the Perifit Care+ and the predicate device do not raise different questions of safety or effectiveness. A table comparing the key features of the subject and predicate devices is provided below.

Table 1: Substantial Equivalence Table

	X6 Perifit Care+	**Perifit (K221476)**	**Comments**
Indications for Use	The 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.	The Perifit 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.	Identical
User Population	Adult females with urinary incontinence; available over-the-counter	Adult females with urinary incontinence; available over-the-counter	Identical
Technological Characteristics			
Mode of Use	Reusable for single patient	Reusable for single patient	Identical
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	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	Identical

	X6 Perifit Care+	Perifit (K221476)	Comments
	with voluntary kegel exercises.	with voluntary kegel exercises.	
Sensing method	Output from force sensing resistors (wireless).	Output from force sensing resistors (wireless).	Identical
Sensor's placement	Inside the rigid plastic enclosure	Inside the rigid plastic enclosure	Identical
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	Similar, new materials supplier
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.	Identical
User Interface	Smartphone GUI	Smartphone GUI	Identical
Anatomical Sites	Female Pubococcygeus muscle area	Female Pubococcygeus muscle area	Identical
External shape	Two egg shaped sensing areas with a tail	Two egg shaped sensing areas	Similar
Shaft length	87.5 mm	90 mm	Similar
Weight	Probe weight: 40g	Probe weight: 54g	Similar
Power Source	Non-rechargeable CR2032 Panasonic batteries, Voltage 3.0VDC	Non-rechargeable CR2032 Panasonic batteries, Voltage 3.0VDC	Identical
Safety Features	Electronics and internal parts sealed in a medical grade silicone shell	Electronics and internal parts sealed in a medical grade silicone shell	Identical

	X6 Perifit Care+	Perifit (K221476)	Comments
Electrical Safety	Tested in accordance with IEC 60601-1-2 and IEC 60601-1	Tested in accordance with IEC 60601-1-2 and IEC 60601-1	Perifit Care+ includes updates to internal electronics to accommodate the modified probe shape and an added accelerometer.
Biocompatibility	Biocompatible - tested in accordance with ISO10993 standards	Biocompatible - tested in accordance with ISO10993 standards	Identical
Software	Smartphone app compatible for iOS and Android	Smartphone app compatible for iOS and Android	Perifit Care+ includes updates to the software of the Perifit App and embedded firmware
Sterilization	Non-sterile device	Non-sterile device	Identical

Summary of Non-Clinical Performance Testing

The patient contacting materials in the Perifit Care+ have been tested in accordance with ISO 10993 standards and was found to be safe for the intended purpose. Biocompatibility testing included Cytotoxicity (ISO 10993-5, 2009), Sensitization (ISO 10993-10, 2010), Vaginal Irritation (ISO 10993-10, 2010), and Systemic Toxicity (ISO 10993-11, 2006). Electrical safety and electromagnetic compatibility testing have been conducted in accordance with IEC 60601-1, IEC 60601-1-2, and IEC 60601-1-11 to establish the safety of the device and FDA guidance documents “Electromagnetic Compatibility (EMC) of Medical Devices” and “Radio Frequency Wireless Technology in Medical Devices” . Software verification and validation testing has also been conducted in accordance with FDA guidance (Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices) and IEC 62304:2006. Cybersecurity has been evaluated in accordance with FDA guidance document Content of Premarket Submissions for Management of Cybersecurity in Medical Devices”. In addition, various mechanical tests have been conducted which support substantial equivalence including mechanical drop testing, durability testing, and sensor behavior testing. The new device attribute, i.e., the tail for use in removing the device was tested tail bending and resistance testing. User testing through a questionnaire supports that users understand the key labeling provisions and how to operate the device.

Conclusions

The Perifit Care+ is as safe and effective as the Perifit. The Perifit Care+ has the same intended use and similar indications for use, technological characteristics, and principles of operation as the predicate device. In addition, the technological differences between the Perifit Care+ and the predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the Perifit Care+ is as safe and effective as the Perifit. Thus, the Perifit Care+ is substantially equivalent.