



Food and Drug Administration
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July 11, 2016

Analytica Ltd.
% Tammy Ahmadzada
Senior Consultant
Brandwood Biomedical
Suite 5, Level 9, 1 Chandos Street
St. Leonards, NSW 2065
Australia

Re: K160758
Trade/Device Name: PeriCoach OTC
Regulation Number: 21 CFR§ 884.1425
Regulation Name: Perineometer
Regulatory Class: II
Product Code: HIR
Dated: March 29, 2016
Received: April 12, 2016

Dear Tammy Ahmadzada:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Joyce M. Whang -S

for

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

Indications for Use

510(k) Number (if known)

K160758

Device Name

PeriCoach OTC

Indications for Use (Describe)

The PeriCoach® OTC 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.

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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Date Prepared: 29 February 2016

510(k) Owner: Analytica Pty Ltd
320 Adelaide Street,
Brisbane, QLD 4000,
Australia
Tel: +61 (0) 732781950

Application Contact: Tammy Ahmadzada
Suite 5, 1 Chandos St
St Leonards NSW 2065
Australia
Tel: +61(0) 299062984
Fax: +61(0) 285804613
tammy@brandwoodbiomedical.com

Trade Name: PeriCoach® OTC

Common Name: Perineometer

Classification Name: (21CFR 884.1425) Perineometer

Product Code: HIR

Predicate: PeriCoach® (K143580)

Intended Use: The PeriCoach® OTC 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.

Device Description: The PeriCoach® OTC 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.

Non-clinical Testing: Biocompatibility
The patient contacting material in the PeriCoach® OTC have been tested in accordance with ISO 10993 standards and found to be safe for the intended purpose. Biocompatibility testing included

Cytotoxicity, Sensitization, Vaginal Irritation, and Systemic Toxicity.

Software

The software used in the PeriCoach OTC was evaluated in accordance with the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005.

Electrical Safety and EMC

The PeriCoach OTC was evaluated in accordance with the following standards IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, and IEC 62133. The PeriCoach OTC meets the respective standards for electrical safety and EMC to establish the safety of the device.

Bench testing

Various mechanical tests have also been conducted to establish the safety of the device. The following bench tests were completed:

- Drop test
- Durability test
- Immersion/long term cleaning exposure
- Sensor behavior test

The bench testing established that the PeriCoach OTC met all of the acceptance criteria needed to demonstrate substantial equivalence.

Clinical Testing:

A post market user survey to substantiate the safety and effectiveness of the subject device for OTC use was provided. Although this type of information is not typically required for the review of OTC perineometer devices, the survey information was reviewed to further substantiate the substantial equivalence determination. The post market user survey demonstrated that the subject device is generally well understood and easy to use without supervision. The survey does not raise any concerns with OTC use of the device.

Summary of Basis for Substantial Equivalence:

Parameters	Predicate: PeriCoach® (K143580)	PeriCoach® OTC (Proposed device)
Mode of Use	Reusable for single patient	Same
Target Population	Adult female urinary incontinence patients	Same
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.	Same
Sensing method	Output from force sensing resistors.	Same
Parameter monitored	Analogue to digital output of uncalibrated force exerted against external walls of device by pubococcygeus and puborectalis muscles.	Same
User Feedback	Provides real-time feedback, via an application on the user's Android or iOS smartphone. The smartphone application displays the relative magnitudes of pelvic muscle contraction or graphically displays the normalized analogue to digital sensor output depending on which option is selected.	Same
Anatomical Sites	Female Pubococcygeus muscle area	Same

Over the Counter	No, prescription only	Yes
Energy used and/or delivered	The device is not intended to deliver energy to the patient. Energy is used to operate the device and communicate the results.	Same
Compatibility with environment and other devices	Probe is not known to conflict with other devices or cause environmental hazards and tested in accordance with IEC60601-1-2 (2007)	Same
Sterility	Non-sterile device	Same
Body Materials	Medical grade silicone	Same
Biocompatibility of body material	Biocompatible in accordance with ISO10993	Same
Electrical Safety	Tested in accordance with IEC60601-1-2 (2007) and IEC60601-1(2005)	Same
Chemical Safety	Probe outer surface constructed of chemically inert materials and tested in accordance with ISO10993	Same
Construction	Rigid polymer structure enclosed within a medical grade silicone outer layer	Same

Conclusion: The predicate and proposed devices share the same indications for use, usage environments, outer construction materials and general principle of operation. The devices are all single patient, reusable and non-sterile.

The primary differences between the predicate device and the proposed device are:

- the original PeriCoach® predicate device was prescription use only and the new PeriCoach® OTC device will be available as an over the counter device;
- Software and firmware upgrades have been made to improve functionality

A Post Market Surveillance Report supports the decision to change the availability of the PeriCoach® device from prescription to over-the-counter. Non-clinical testing demonstrates that the PeriCoach® OTC device raises no

new safety or efficacy concerns and is therefore substantially equivalent to the legally marketed predicate devices.