DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 18, 2015

Analytica Ltd
% Tracey Bullivant
Consultant
Brandwood Biomedical
408, 460 Pacific Highway
St Leonards, NSW 2065 AU

Re: K143580
Trade/Device Name: PeriCoach
Regulation Number: 21 CFR 884.1425
Regulation Name: Perineometer
Regulatory Class: Class II
Product Code: HIR
Dated: December 12, 2014
Received: December 18, 2014

Dear Tracey Bullivant,

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 Fisher
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)*
K143580

Device Name
PeriCoach

Indications for Use *(Describe)*
The PeriCoach 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.

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510(k) Summary

Date Prepared: 13 December, 2014

510(k) Owner: Analytica Pty Ltd
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Trade Name: PeriCoach®

Common Name: Perineometer

Classification Name: (21CFR 884.1425) Perineometer

Product Code: HIR

Predicate: Neen Healthcare Periform (K002617)

Intended Use: The PeriCoach® 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® 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 under prescription only.

Non-clinical Testing: The patient contacting materials in the PeriCoach have been tested in accordance with ISO 10993 standards and found to be safe for the

intended purpose. Biocompatibility testing includes 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 60601-1:2005, IEC 60601-1-2:2007, and IEC 60601-1-11:2010 to establish the safety of the device. Software verification and validation testing has also been conducted in accordance with IEC 62304:2006.

In addition, various mechanical tests have been conducted to establish substantial equivalence including mechanical drop testing, durability testing, immersion/long term cleaning exposure, and sensor behavior testing. The results of these tests indicate that the device is effective for the intended use.

Summary of Basis for Substantial Equivalence:

Parameters	Predicate: Periform (K002617)	PeriCoach (New 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
Electrode/sensor orientation	Longitudinal	Same
Sensing method	sEMG biofeedback recording (wired electrode).	Output from force sensing resistors (wireless).
Parameter monitored	Aggregate surface electromyogram (sEMG).	Analogue to digital output of uncalibrated force exerted against external walls of device by pubococcygeus and puborectalis muscles.

Parameters	Predicate: Periform (K002617)	PeriCoach (New device)
User Feedback	The Periform does not provide feedback directly to the user; a separate external feedback device is required.	The PeriCoach is designed to provide real-time feedback, via an application on the user's 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.
Anatomical Sites	Female Pubococcygeus muscle area	Same
Where used	Hospitals, Clinics, Doctors' offices or home use under Clinician supervision	Same
Energy used and/or delivered	No energy used or delivered, only transported[1]	The device is not intended to deliver energy to the patient. Energy is used to operate the device and communicate with the Smartphone Application.
Compatibility with environment and other devices	Probe is not known to conflict with other devices or cause environmental hazards	Same – the PeriCoach device has been tested in accordance with IEC60601-1-2 (2007)
Sterility	Probe does not need to be sterile. Appropriate cleaning procedure included in instructions for use.	Same
Body Materials	BP Empera Impact Polystyrene Type 514	Medical grade silicone
Biocompatibility of body material	Biocompatible	Same - tested in accordance with ISO10993 standards
Electrical Safety	Unknown	Tested in accordance with IEC60601-1-2 (2007) and IEC60601-1(2005)
Chemical Safety	Body and electrodes constructed of chemically inert materials	Probe outer surface constructed of chemically inert materials and tested in accordance with ISO10993 standards.
Construction	Two mouldings enclosing two electrodes, ultrasonically welded together	Rigid polymer structure enclosed within a medical grade silicone outer layer
Shaft length	76 mm	Same

[1] Wording taken directly from 510(k) summary for Periform, K002617

Parameters	Predicate: Periform (K002617)	PeriCoach (New device)
Width across electrodes/ sensors	34 mm	30-35 mm, across region containing sensor
Maximum flange dimension	28.2 mm	30-35 mm
Electrode surface area	4.9cm2 x 2	Sensor surface area is 11.8cm2
Prescription only device	Yes	Same

Conclusion: Both devices share common indications for use, usage environments and general principle of operation. The devices are both single patient reusable, non-sterile and are available by prescription only.

The main differences between the devices are the way the pelvic floor muscle activity is determined, the materials used and the method of feedback to the user. Non-clinical testing demonstrates that the PeriCoach device raises no new safety or efficacy concerns and is therefore substantially equivalent to the legally marketed predicate device.