DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 29, 2017

Ralston Group
% Jennifer Tillman
Business Coordinator
Intertek Surveying Services
16441 Space Center Blvd, Suite D-100
Houston, TX 77058

Re: K171896
Trade/Device Name: Feminine Personal Trainer (FPT)
Regulation Number: 21 CFR§ 884.1425
Regulation Name: Perineometer
Regulatory Class: II
Product Code: HIR
Dated: June 7, 2017
Received: June 26, 2017

Dear Jennifer Tillman:

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 (DICE) 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 (DICE) 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,

Benjamin R. Fisher -S

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

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)*
K171896

Device Name

Feminine Personal Trainer (FPT)

Indications for Use *(Describe)*

The Feminine Personal Trainer (FPT) is indicated for the strengthening of the perineal pelvic floor muscles by providing resistance to an individual's voluntary contractions of these muscles. It seeks to correct, through exercise, urinary incontinence in women.

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

I. SUBMITTER

Ralston Group
656 Lake Lanier Rd.
Selma, AL 36701

Phone: 334-875-2298

Contact Person: Russell Ralston
Date Prepared: August 16, 2017

II. DEVICE

Name of Device:	Feminine Personal Trainer (FPT)
Common or Usual Name:	Kegel Exercise and Pelvic Floor Workout Device
Classification Number:	21 CFR § 884.1425
Classification Name:	Perineometer
Regulatory Class:	II
Product Code:	HIR (Perineometer)
Classification Panel:	Obstetrics/Gynecology

III. PREDICATE DEVICE

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K121902	NatraTone®	Orelle Corporation Ltd

This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The FPT is designed specifically for women for their use in strengthening the pelvic floor musculature. It is a single, reusable, home-use device that comes into contact with the vaginal mucosal membrane for a limited (< 24 hours) duration per each use.

The FPT is an hourglass-shaped device made from surgical stainless steel. The FPT is available in three sizes: standard, small and petite.

The FPT is inserted into the vagina and is held in place by contracting the pelvic floor muscles. The hourglass shape ensures automatic positioning so that the appropriate muscles are targeted. The weight of the FPT provides resistance as it is gently lifted with each contraction of

the pelvic floor muscles. When utilized correctly, the device will move upward and inward when the user contracts her pelvic floor muscles. The body's angle while exercising controls the level of resistance.

V. INDICATIONS FOR USE

The Feminine Personal Trainer (FPT) is indicated for the strengthening of the perineal pelvic floor muscles by providing resistance to an individual's voluntary contractions of these muscles. It seeks to correct, through exercise, urinary incontinence in women.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Device Name	**Feminine Personal Trainer (FPT)**	**NatraTone®**	**Device Comparison**
510(k) Number	K171896	K021115	Not applicable
Regulation Number	21 CFR § 884.1425	21 CFR § 884.1425	Same
Product Code	HIR	HIR	Same
Classification Name	Perineometer	Perineometer	Same
Indications for Use	The Feminine Personal Trainer (FPT) is indicated for the strengthening of the perineal pelvic floor muscles by providing resistance to an individual's voluntary contractions of these muscles. It seeks to correct, through exercise, urinary incontinence in women.	NatraTone® is indicated for the strengthening of the perineal pelvic floor muscles by providing resistance to an individual's voluntary contractions of these muscles. It seeks to correct, through exercise, Urinary Incontinence in women.	Same
Over the Counter (OTC)	Yes	Yes	Same
Feature	Resistive vaginal exerciser	Resistive vaginal exerciser	Same
Target Population	Women with mild incontinence	Women with mild incontinence	Same
Anatomical Site	Vagina	Vagina	Same
Single Patient Device	Yes	Yes	Same
Reusable	Yes	Yes	Same
Sterile	Clean, but not sterile	Clean, but not sterile	Same
Device Design	Hourglass-shaped	Symmetrically S-shaped	Same
Materials	Surgical stainless steel grade 303	Molded medical grade polycarbonate	Different

Device Name	**Feminine Personal Trainer (FPT)**	**NatraTone®**	**Device Comparison**
Dimensions	Standard FPT: Large end diameter: 1.628 in Small end diameter: 1.248 in Length: 3.503 in Weight: 450 g. Small FPT: Large end diameter: 1.500 in Small end diameter: 1.125 in Length: 3.500 in Weight: 340 g Petite FPT: Large end diameter: 1.250 in Small end diameter: 1.100 in Length: 4.564 in Weight: 340 g.	Length: 3.25 in Width at bulbous base end: 1.35 in Weight: 1 oz (28 g)	Different
Packaging	The FPT device is packaged in a velveteen bag inside a clear plastic tube with instructions and exercise chart.	NatraToner intra-vaginal training aid is packaged inside of a translucent carry-case; an instruction book with activity diary and a personal training DVD are all provided in a cardboard box.	Same
Operating Principle	Resistive pelvic floor strengthener	Resistive pelvic floor strengthener	Same
Resistive Component	Weight	Symmetrically S-shaped	Different
Instructions for Use	Manual and video link	Manual	Same

Except for materials, dimensions, and resistive component, all the other device attributes are the same as the predicate device. Nonclinical performance testing has been done to indicate the materials are safe. By using weight as the resistive component, the FPT devices have different dimensions to provide different levels of resistance to individuals instead of a single level of resistance from the predicate device. The minor differences in the technological characteristics between the FPT and the predicate device do not raise different questions of safety or effectiveness.

VII. Non-clinical Performance Testing

Non-clinical performance testing was done utilizing the following standards:

- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity

- ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization, Vaginal Irritation and Guinea Pig Maximization Sensitiziation

Test results from the tests listed above supported that the device is not cytotoxic, not irritating, and not sensitizing. The FPT device has been demonstrated to be biocompatible.

VIII. CONCLUSIONS

The FPT device has the same intended use as the predicate. Performance testing of the device supports that the FPT device is as safe and effective as the predicate. Therefore, the FPT device is substantially equivalent to the predicate.