August 24, 2020

Plus EV Holdings dba Intimate Rose
% Elizabeth Proctor
Consultant
Q-Metrics LLC
860 Lindenwood Lane
Medina, OH 44256

Re: K193364
Trade/Device Name: Intimate Rose Kegel Exercise System
Regulation Number: 21 CFR§ 884.1425
Regulation Name: Perineometer
Regulatory Class: II
Product Code: HIR
Dated: July 20, 2020
Received: July 23, 2020

Dear Elizabeth Proctor:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Monica D. Garcia, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Indications for Use *(Describe)*

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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"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 – K193364

I. SUBMITTER

Submitted by: Plus EV Holdings dba Intimate Rose
1700 Iron Street
North Kansas City, MO 64116
Phone: 816-805-6722
Contact Person: Aaron Wilt

Date Prepared: August 21, 2020

II. DEVICE

Device Name: Intimate Rose Kegel Exercise System
Common Name: Kegel Exercise and Pelvic Floor Workout
Device Regulation Number: 21 CFR § 884.1425
Regulation 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
K171896	Feminine Personal Trainer (FPT)	Ralston Group

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

IV. DEVICE DESCRIPTION

The Intimate Rose Kegel Exercise System is a pelvic floor exercise device for use in strengthening the pelvic floor musculature. It is a reusable, over-the-counter device that is comprised of 6 progressively heavier and color-coded silicone weights. An Intimate Rose

Kegel Exercise System weight is inserted into the vagina and is held in place by contracting the pelvic floor muscles. The weight of the Intimate Rose Kegel Exercise System device provides resistance as it is 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 Intimate Rose Kegel Exercise System 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, low tone in the pelvic floor, which can cause or contribute to health issues including urinary incontinence and sexual dysfunction.

VI. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	APPLICANT DEVICE	PREDICATE DEVICE
Device Name	Intimate Rose Kegel Exercise System	Feminine Personal Trainer (FPT)
510(k) Number	K193364	K171896
Regulation Number	21 CFR§ 884.1425	21 CFR§ 884.1425
Regulation Name	Perineometer	Perineometer
Regulatory Class	II	II
Product Code	HIR	HIR
Indications for Use	The Intimate Rose Kegel Exercise System is indicated for the strengthening of the perineal pelvic floor muscles by providing resistance to an individual's voluntary contractions of these muscles. It	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
	APPLICANT DEVICE	PREDICATE DEVICE

	seeks to correct, through exercise, low tone in the pelvic floor, which can cause or contribute to health issues including urinary incontinence and sexual dysfunction.	muscles. It seeks to correct, through exercise, urinary incontinence in women.
Over the Counter	Yes	Yes
Anatomical Site	Vagina	Vagina
Single Patient Device	Yes	Yes
Reusable	Yes	Yes
Sterile	No	No
Device Design	Egg shaped with tail to remove the device	Hourglass-shaped
Materials	Silicone, stainless steel	Stainless steel
Dimensions	Six varying weights {25g, 40g, 60g, 85g, 105g and 125g), each: Main Section of Device - Length: 2.5 inches/62mm, Diameter {widest point): 1 inch/23mm Tail Section of Device - Length: 3.15 inches/80mm, Diameter: 3mm body of tail, 5mm bulb end of tail	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.
Packaging	The Intimate Rose Kegel Exercise System is packed with 6 weights in a cardboard box with protective foam. It includes a detailed instruction guide and travel bag.	The FPT device is packaged in a velveteen bag inside a clear plastic tube with instructions and exercise chart.
Color	Shades of white, pink, and purple	Stainless steel

The indications for use of the subject device and predicate device are similar. The subject device and the predicate device have the same intended use for strengthening pelvic floor muscles.

The subject and predicate device have different technological characteristics, including different materials, shapes, dimensions, and weight options. The technological differences between the subject and predicate device do not raise different types of safety and effectiveness questions.

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

The following non-clinical performance information was provided for the subject device

Biocompatibility

- Cytotoxicity testing per ISO 10993-5:2009
- Guinea pig maximization sensitization testing per ISO 10993-10:2010
- Vaginal irritation testing per ISO 10993-10:2010

Reprocessing

Information per FDA's 2015 Guidance Document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"

Mechanical Performance

- Joint strength testing

VIII. CONCLUSION

Based on the results of the performance testing described above, the Intimate Rose Kegel Exercise System is as safe and effective as the predicate device and supports a determination of substantial equivalence.