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

September 10, 2014

LELO, Inc.
% Kevin Walls
Principal Consultant
Regulatory Insight, Inc.
33 Golden Eagle Lane
Littleton, CO 80127

Re: K140780
Trade/Device Name: Kegel Smart, KegelSmart Pearl
Regulation Number: 21 CFR§ 884.1425
Regulation Name: Perineometer
Regulatory Class: II
Product Code: HIR
Dated: June 17, 2014
Received: June 18, 2014

Dear Kevin Walls,

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Herbert P. Lerner -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

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)*
K140780

Device Name
Intimina KegelSmart and Intimina KegelSmart Pearl

Indications for Use *(Describe)*
The Intimina KegelSmart and Intimina KegelSmart Pearl are intended for independent use by women at home to strengthen pelvic floor muscles to treat stress and/or urge urinary incontinence.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

LELO USA
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9 September 2014

Contact Person

Pavle Sedic
President, LELO Inc.
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Device Name

Trade name: Intimina KegelSmart (model 1), Intimina KegelSmart Pearl (model 2)
Common name: Pelvic floor muscle exercise device

Device Classification

Obstetrics and gynaecology panel, Perineometer 884.1425, product code HIR, class II device

Indications for Use Statement

The Intimina KegelSmart and Intimina KegelSmart Pearl are intended for independent use by women at home to strengthen pelvic floor muscles to treat stress and/or urge urinary incontinence.

Device Description

The Intimina KegelSmart and KegelSmart Pearl are pelvic floor muscle exercise devices that provides biofeedback and exercise guidance. Each time the device is used it registers the user's pelvic floor muscle contraction strength and automatically sets a strength level, from 1 to 5, for the following session. Each level has a corresponding exercise routine that is communicated to the user with gentle vibrations.

Statement of Substantial Equivalence

The Intimina KegelSmart and KegelSmart Pearl are substantially equivalent to The Reflex Treatment System (DesChutes Medical Products, Inc.) clearance number K994079.

Comparison of Technological Characteristics with the Predicate Device

Name of the device	**KegelSmart and KegelSmart Pearl**	**The Reflex Treatment System**
FDA classification	Class II, perineometer 884.1425 (HIR)	Class II, perineometer 884.1425 (HIR)
Intended use	For the treatment of stress and/or urge urinary incontinence in females	For the treatment of stress and/or urge urinary incontinence in females
Target population	Women experiencing symptoms of pelvic floor muscle weakness and mild incontinence	Women experiencing symptoms of pelvic floor muscle weakness and mild incontinence
Anatomical site	Probe inserted vaginally	Probe inserted vaginally
Method of function	Registers the user's pelvic strength and assigns a strength level. Guides the user through exercise routines (with vibration).	Registers the user's pelvic strength and assigns a strength level. Guides the user through exercise routines (with visual cues).
System components	Vaginal probe covered in medical grade silicone	Balloon sensor vaginal probe plus LCD monitor
Biofeedback mechanism	Electric resistance strain gauge	MEMS Air pressure sensor
Prescription device	No	No
Medical practice or home use?	Home use	Home use
Is the device provided sterile?	Clean but not sterile	Clean but not sterile
Does the device use software?	Yes	Yes
Assistance from medical personnel required	No	No
Single patient device	Yes	Yes
Materials	Medical grade silicone	Medical grade silicone
Energy used	1 x AAA battery 1.5V	2 x AA batteries 3.0V

Name of the device	KegelSmart and KegelSmart Pearl	The Reflex Treatment System
Electrical safety	ETL/cETL IEC/EN 60601-1 3rd ed., IEC/EN 60601-1-2:2007	UL2601-1, 2nd Edition, EN60601-1-2:1993
Pelvic floor muscle exercise routine	Combination of rapid contract and release exercises and longer contract and release exercises. Routine difficulty increases with strength levels.	Combination of rapid contract and release exercises and longer contract and release exercises
Strength levels	5 levels (can move up and down levels)	3 levels (can move up and down levels)
Resistance	Non-variable resistance	Non-variable resistance

Summary of Differences in Technological Characteristics

The subject and predicate device do not have the same technological characteristics. The different technological characteristics between the subject and predicate device are as follows:

- Measurement of contraction strength – The subject devices use an electric resistance strain gauge, and the predicate device uses a MEMS air pressure sensor.
- Levels of resistance – The subject devices have five levels of resistance, and the predicate device has three.
- Feedback mechanism – The subject devices use vibrations to prompt the user to contract their pelvic floor muscles, whereas the predicate device uses visual cues on an LCD screen.
- Exercise routines – The subject and predicate devices utilize different exercise routines.

The different technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness, as pelvic floor muscle exercise devices often vary with respect to their measurement of contraction strength, levels of resistance, feedback mechanism, and exercise routines.

Summary of Performance Data of KegelSmart and KegelSmart Pearl

There is evidence in the published literature that regular pelvic floor muscle training results in a significant increase in pelvic floor muscle strength, is an effective treatment for stress or mixed urinary incontinence.

Intimina KegelSmart and KegelSmart Pearl (model 1 and 2) are in conformity with the applicable requirements of the following documents:

Ref. No.	Title
ISO 10993-5	Biological evaluation of medical devices Part 5 Tests in vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices. Part 10: Tests for irritation and skin sensitization
IEC 60601-1 3rd ed.	Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2: 2007	Medical electrical equipment –Part 1-2:General requirements for safety –Collateral standard: Electromagnetic compatibility –Requirements and tests

The software for the Intimina KegelSmart and KegelSmart Pearl is in line with the recommendations outlined in the FDA guidance document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued in final on May 11, 2005.

Functional performance testing was provided on the Intimina KegelSmart and KegelSmart Pearl demonstrating that it operates per its Instructions for Use.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the Intimina KegelSmart and Intimina KegelSmart Pearl are substantially equivalent to the proposed predicate device.