Lilium Otsuka Co., Ltd.
% Kathryn Coressel, RAC
Senior Regulatory Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
AUSTIN TX 78746

December 7, 2017

Re: K170046
Trade/Device Name: Lilium α-200E
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: October 30, 2017
Received: November 3, 2017

Dear Ms. Coressel:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*

K170046

Device Name

Lilium α-200E

Indications for Use *(Describe)*

Lilium α-200E, using ultrasound, is intended to provide the diagnostic information of the visualized urine dynamics acquired from the volume of the urinary bladder.

Clinical Application: Track 1 Only, Other- Abdominal
Mode of Operation: Mode A

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."

Diagnostic Ultrasound Indications For Use

(Per Appendix G, FDA Ultrasound Guidance)

510(k) Number: TBD

Device Name: Lilium α-200E Ultrasound System

Intended Use: Lilium α-200E, using ultrasound, is intended to provide the diagnostic information of the visualized urine dynamics acquired from the volume of the urinary bladder.

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (A-Mode)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Bladder)							N
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral vessel	Peripheral Vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging.

510(k) Summary

Lilium α-200E

K170046

1. Submission Sponsor

Lilium Otsuka Co., Ltd.
4-12-6, Chiyoda
Chuo-ku, Sagamihara City,
Kanagawa
252-0237
JAPAN
Hiroaki Takahashi
Manager
Email: htakahashi@liotsuka.com
Office number: +81-42-704-3822

2. Submission Correspondent

Emergo Global Consulting, LLC

2500 Bee Cave Road

Building 1, Suite 300

Austin, TX 78746

Office Phone: (512) 327.9997

Contact: Kathryn A Coressel, RAC

Title: Senior Consultant, RA

3. Date Prepared

12/29/2016

4. Device Identification

Trade/Proprietary Name: Lilium α-200E

Common/Usual Name: IYO: Ultrasonic pulsed echo imaging system
ITX: Diagnostic ultrasonic transducer

Regulation Number:	IYO: 21 CFR 892.1560 ITX: 21 CFR 892.1570
Product Code:	IYO and ITX
Device Class:	Class II
Classification Panel:	Radiology

5. Legally Marketed Predicate Device(s)

K071217, BladderScan® BVI 9400 Ultrasound System, Verathon Inc.

6. Indication for Use Statement

Lilium α-200E, using ultrasound, is intended to provide the diagnostic information of the visualized urine dynamics acquired from the volume of the urinary bladder.

7. Device Description

Lilium α-200E is a portable, battery powered, software controlled ultrasound system used to acquire and display real time A-mode images of the bladder. The Lilium device consists of a main body and an ultrasonic probe. Lilium device is used to measure urine volume inside the bladder non-invasively. In addition, it provides urine volume in the bladder at regular intervals and graphically displays the gradual increase of urine collection. It alerts when a set volume is attained. The device retains history. This information aids healthcare professionals, patients, and caregivers in providing proper continence care for those with urination difficulties. The device has wireless capabilities.

The Lilium device measures urine volume by means of a probe that has four ultrasound sensors aligned vertically. The sensor aligned side is applied to outside the abdomen wall so the probe can emit ultrasound (Mode A) toward the bladder and receive the echoed signals. The device then analyzes the signal intensity to measure the height and depth of the bladder. These measurements determine the size of the bladder and quantify the filling of the bladder (urine volume). This volume is displayed on the screen. The system also includes indicator lights to indicate for urine volume and for correct positioning of the device.

The operating principle of the device is as follows:

An ultrasonic probe in which ultrasound transducers are arranged is placed on the abdominal surface, above the pubic bone, along the extending direction of the urinary bladder. When the ultrasound is transmitted from the probe, transducers put on the base part of the bladder detect echoes or ultrasonic reflections first when the urine begins to accumulate. As the bladder volume increases, transducers on the upper bladder detect echoes.

8. Substantial Equivalence Discussion

The following table compares the Lilium α-200E to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics

Manufacturer		**Verathon. Inc.**	**Comparison to Predicate**
Trade Name	**Lilium α-200E**	**BladderScan® BVI 9400**	
Indications for use:	Lilium α-200E, using ultrasound, is intended to provide the diagnostic information of the visualized urine dynamics acquired from the volume of the urinary bladder.	The BladderScan® BVI 9400 is intended to project ultrasound energy through the lower abdomen of the nonpregnant patient to obtain an image of the bladder and uses that image to calculate the bladder volume noninvasively.	Minor differences in wording do not raise any additional questions of safety or efficacy.
Contraindications	Lilium α-200E is not intended for: 1. patients who have unhealed wounds in the lower abdomen area 2. patients for whom a physician considers the use of the device to be inappropriate 3. pregnant patients 4. Infants 5. patient with ascites	The BladderScan BVI 9400 is not intended for fetal use or for use on pregnant patients. Do not use the BladderScan BVI 9400 on: A patient who has open skin or wounds in the suprapubic area. A patient with ascites. A pregnant patient.	Minor wording differences do not raise any additional questions of safety or efficacy.
Patient/User Characteristics			
Target Population	Male, Female, and Pediatric patients (7 years of age and older)	Same	Same
Anatomical Site	Bladder	Same	
Users	Physicians/Medical Professionals	Same	
Technological Characteristics and Performance			
Patient Contact Material	UMGABS Acrylonitrile Butadiene Styrene Plastic (ABS) VW800 (colorant: WUA4368A White DIC583)	Low Density Polyethylene Plastic (LDPE) Dow 955i (colorant: Techmer PM 84149 Cool Grey 4C)	Biocompatibility test results support that the material is safe for the intended use.

Manufacturer		Verathon. Inc.	Comparison to Predicate
Trade Name	**Lilium α-200E**	**BladderScan® BVI 9400**	
Power Source	Electrical (AA Battery)	electrical (lithium-ion battery)	Difference in commercial battery type does not raise any additional questions of safety or efficacy.
Energy Delivered	Ultrasound	Same	Same
Measurement Accuracy	± (15% ±20mL)	± 15% ± 15mL	Difference does not raise any additional questions of safety or efficacy.
Measurement Range	1 to 999 mL	0 to 999 mL	Difference does not raise any additional questions of safety or efficacy.
Modes of Operation	A-mode	B -mode	*See discussion below
Transducer Resonant Frequency	3MHz +/- 20%	2.95 MHz	Difference does not raise any additional questions of safety or efficacy.
Center Frequencies	3MHz	3.0 / 1.74 MHz	The lower frequency for the predicate does not raise any additional questions of safety or efficacy. Proposed device meets FDA's requirement.
Safety Standards			
Acoustic Output: Maximum Mechanical Index (MI)	≤ 1.9	0.95	Difference does not raise any additional questions of safety or efficacy.
Acoustic Output: Intensity, Spatial Peak Temporal Average (ISPTA)	I_{SPTA} = not more than 720mW/cm^2	≤ 1.0 mW/cm^2	Difference does not raise any additional questions of safety or efficacy.

Manufacturer		Verathon. Inc.	Comparison to Predicate
Trade Name	**Lilium α-200E**	**BladderScan® BVI 9400**	
Biocompatibility Standard Compliance	ISO 10933-1:2009	Same	Same
Thermal Safety	IEC60601-2-37:2007	Same	
Electrical Safety Standard Compliance	IEC 60601-1:2005/A1:2012	Same	
Electromagnetic Compatibility Standard Compliance	IEC 60601-1-2:2007	Same	

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of Lilium α-200E and in showing substantial equivalence to the predicate device, Lilium Otsuka Co., Ltd. completed a number of non-clinical performance tests. The Lilium α-200E meets all the requirements for overall design, biocompatibility, performance, and electrical safety results confirming that the design output meets the design inputs and specifications for the device.

The Lilium α-200E passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility testing per ISO 10993-1
- Electrical safety testing per IEC 60601-1 and IEC 60601-2-37
- Electromagnetic Disturbance (EMD) testing per IEC 60601-1-2
- Acoustic Output Measurement Report 60601-2-37
- Thermal Measurement Report 60601-2-37
- Software verification and validation IEC 62304
- Storage and Transport Testing
- JIS T 1501-General methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment
- EN 62366:2008 Usability engineering to medical devices

10. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device(s).

The Lilium α-200E, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.