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

Verathon Incorporated
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
BUFFALO MN 55313

September 15, 2017

Re: K172356
Trade/Device Name: BladderScan® PRIME PLUS system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: September 5, 2017
Received: September 6, 2017

Dear Mr. Job:

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,

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)*

K172356

Device Name
BladderScan® PRIME PLUS system

Indications for Use *(Describe)*
The BladderScan® PRIME PLUS system is an ultrasound device intended to be used for measuring urine volume of the bladder non-invasively.

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.

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Diagnostic Ultrasound Indications for Use Form

System: BladderScan® PRIME PLUS system
Transducer: N/A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P						
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P						
	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 (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Bladder)	P						

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

All items marked "P" were previously cleared in 510(k) K153101

Prescription Use (21 CFR 801.109)

_____
(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number _____

Diagnostic Ultrasound Indications for Use Form

System: BladderScan® Prime PLUS System
Transducer: 2.49 MHz / 1.72 MHz

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P						
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P						
	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 (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Bladder)	P						

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

All items marked "P" were previously cleared in 510(k) K153101

Prescription Use (21 CFR 801.109)

_____
(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number _____

510(k) Summary of Safety and Effectiveness

This summary of Safety and Effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR 807, Subpart E, section 807.92.

Date Prepared: June 29, 2017

1. **Submitter's name, address, telephone number, contact person:**

Verathon Inc.
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Swapna Chirala
Regulatory Compliance Engineer, Regulatory Affairs and Quality Assurance
Phone: 425.629.5582
Email: Swapna.Chirala@verathon.com

2. **Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:**

Common Name:	Diagnostic Ultrasound System with accessories
Proprietary/Trade name:	BladderScan® PRIME PLUS system
Device Class:	Class II
Review Panel:	Radiology

Classification Information:

Name	CFR Section	Product Code
Ultrasonic Pulsed Echo Imaging System	21 CFR 892.1560	IYO
Diagnostic Ultrasound Transducer	21 CFR 892.1570	ITX

3. Identification of the predicate or legally marketed device:

BladderScan® PRIME System K153101

4. Device Description:

The BladderScan® PRIME PLUS system provides non-invasive measurement of urinary bladder volume. The system calculates the bladder volume using patented neural network technology. Volume measurements made with this technology are based on a more complex, multifaceted image of the bladder.

Bladder volume, directional aiming with real-time feedback, battery status and usage rate indicators are displayed on the LCD display. The system operates using a battery which includes a charging cradle.

5. Intended Use:

The BladderScan® PRIME PLUS System is an Ultrasound device intended to be used for measuring urine volume of the bladder non-invasively.

Clinical Application: Abdominal B-Mode (Bladder)

6. Technological Characteristics:

The BladderScan® PRIME PLUS system and the predicate are both Track 1 devices that employ the same fundamental technology. The comparison table is provided below.

Comparison Category	**Verathon BladderScan® PRIME PLUS System (This submission)**	**Predicate Verathon BladderScan® PRIME System (K153101)**
Comparison Overview		
FDA Ultrasound Guidance Track	Identical to predicate	Track 1

Comparison Category	Verathon BladderScan® PRIME PLUS System (This submission)	Predicate Verathon BladderScan® PRIME System (K153101)
Device Classification Name	Identical to predicate	System, Imaging, Pulsed Echo, Ultrasonic
Intended Use/Indications For Use	Identical to predicate	The BladderScan® Prime System is an ultrasound device intended to be used for measuring the urine volume in the bladder non-invasively.
Contraindications	Identical to predicate	The BladderScan® Prime System is not intended for fetal use or for use on pregnant patients, patients with ascites, or patients with open skin or wounds in the suprapubic region.
Patient/User Characteristics		
Target Population	Identical to predicate	Male, Female, and Pediatric patients
Anatomical Site	Identical to predicate	Bladder
Users	Identical to predicate	Physicians/Medical Professionals
Technological Characteristics and Performance		
Patient Contact Material	Identical to predicate	Lexan Polycarbonate Plastic HP1-1H112 (colorant: PCM 84907 Dark Gray 424C)
Sterility	Identical to predicate	Non-sterile
Power Source	Identical to predicate	Electrical (Lithium-ion battery)
Energy Delivered	Identical to predicate	Ultrasound
Measurement Accuracy	0-100mL = ±7.5mL 100-999 mL = ±7.5%	± 15% ± 15mL
Measurement Range	Identical to predicate	0 to 999 mL
Variable Acoustic Output Settings	Identical to predicate	No
Controls to Change Acoustic Output During Scan	Identical to predicate	No
Modes of Operation	Identical to predicate	B-mode
Transducer Type	Identical to predicate	Mechanical Sector Probe
Transducer Diameter	Identical to predicate	13 mm
Number of Elements	Identical to predicate	1

Comparison Category	Verathon BladderScan® PRIME PLUS System (This submission)	Predicate Verathon BladderScan® PRIME System (K153101)
Transducer Resonant Frequency	Identical to predicate	2.95 MHz
Nominal Acoustic Output Frequencies	Identical to predicate	2.49 / 1.72 MHz
Sector Angle	Identical to predicate	120 degrees
Number of Scan Planes	Identical to predicate	12
Design and Usability Features		
Portable	Identical to predicate	Yes
Display	Identical to predicate	LCD
Scan Button	Identical to predicate	Yes
Touchscreen Operation	Identical to predicate	Yes
Selectable Unit Orientation (Patient Right/Left)	Identical to predicate	Yes
Live Scan Image	Identical to predicate	Yes
Procedure Type selection on user interface	Single mode of operation accommodating Male/Female/Small child	Male/Female/Small Child mode selection screen and If female: Uterus or no uterus selection
Calibration	No Calibration recommended	Annual Calibration recommended
Data Connections	Identical to predicate	USB, SD card
Attached Printer	Identical to predicate	Yes
Accessories	Identical to predicate	Printer, battery, battery charger, power cord, mobile cart
Safety Standards		
Acoustic Output: Maximum Mechanical Index (MI)	Identical to predicate	0.424
Acoustic Output: Maximum Thermal Index (TI)	Identical to predicate	≤ 1.0
Acoustic Output: Intensity, Spatial Peak Temporal Average (I_{SPTA})	Identical to predicate	≤ 1.0 mW/cm^2
Acoustic Output: Intensity, Spatial Peak Pulse Average (I_{SPPA})	Identical to predicate	≤ 12.0 W/cm^2
Biocompatibility Standard Compliance	Identical to predicate	ANSI/AAMI/ISO 10993-1:2009, ANSI/AAMI/ ISO 10993-5:2009, ISO 10993-10:2010, ANSI/AAMI/ISO 10993-12:2012

Comparison Category	Verathon BladderScan® PRIME PLUS System (This submission)	Predicate Verathon BladderScan® PRIME System (K153101)
Electrical Safety Standard Compliance	AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012, IEC 60601-2-37:2007	IEC 60601-1:2005, IEC 60601-2-37:2007
Electromagnetic Compatibility Standard Compliance	Identical to predicate	IEC 60601-1-2: 2007

7. Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The BladderScan® PRIME PLUS system has been evaluated for electrical, thermal, mechanical and EMC safety. Additionally, cleaning/disinfection, biocompatibility, and acoustic output have been evaluated, and the device has been found to conform to applicable voluntary medical device safety standards. Assurance of quality was established by employing the following elements for product development: Design Reviews, Risk Assessment, Development of Requirements and Software Verification, Hardware Verification, and Safety Compliance Verification. Patient contact materials are biocompatible.

The BladderScan® PRIME PLUS system is designed to comply with the following standards:

FDA Consensus Standards

Reference No.	Title
ISO 10993-1:2009	ISO 10993-1:2009/R(2013) Biological Evaluation of Medical Devices. Part 1: Evaluation and Testing
ISO 10993-5:2009	AAMI / ANSI / ISO 10993-5:2009/(R)2014, Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity. (Biocompatibility)
ISO 10993-10:2010	ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation of Medical Devices – Part 10: Test for Irritation and Skin Sensitization. (Biocompatibility)
ANSI/AAMI/ISO 10993-12:2012	AAMI / ANSI / ISO 10993-12:2012, Biological Evaluation Of Medical Devices - Part 12: Sample Preparation And Reference Materials. (Biocompatibility)
IEC 60601-1:2005/A1:2012	AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, Mod). (General II (ES/EMC))
IEC 60601-1-2:2007	AAMI / ANSI / IEC 60601-1-2:2007(R)2012, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests (Edition 3)

IEC 60601-2-37:2007	IEC 60601-2-37:2007 Medical Electrical Equipment. Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment.
AIUM/NEMA UD-2:2004	Standard for Real Time Display of Thermal and Mechanical Acoustic output Indices on Diagnostic Ultrasound Equipment.
AIUM AOMS:2004	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.
ISO 14971:2007	AAMI / ANSI / ISO 14971:2007/(R) 2010 (Corrected 4 October 2007), Medical Devices - Applications of Risk Management to Medical Devices. (General I (QS/RM))

Miscellaneous Standards

Reference No.	Title
IEC 60601-1-6:2010/A1:2013	IEC 60601-1-6 Edition 3.1 2013-10, Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability. (General I (QS/RM))
AAMI HE 75:2009	AAMI/ANSI HE75:2009/(R)2013, Human Factors Engineering – Design of Medical Devices. (General I (QS/RM))
IEC 62366-1:2015	IEC 62366-1 Edition 1.0 2015-02, Medical Devices – Part 1: Application of Usability Engineering to Medical Devices [Including Corrigendum 1 (2016)]. (General I (QS/RM))
ISO 13485:2003	ISO 13485:2003, Medical Devices Quality Management System – Requirements for Regulatory Purposes

Summary of Clinical Tests:
The BladderScan® PRIME PLUS System, subject of this submission, did not require clinical studies to support the determination of substantial equivalence.

8. Conclusion

The intended use and other key features are consistent with traditional clinical practice and FDA guidance. The BladderScan® PRIME PLUS system and the predicate device conform to applicable electro-medical device safety standards with compliance verified through independent evaluation. The BladderScan® PRIME PLUS system and the predicate meet FDA requirements for Track 1 devices, share indications for use, have biosafety equivalence and are manufactured using ISO 13485 quality management system. Verathon Inc. believes that the BladderScan® PRIME PLUS system is substantially equivalent with regard to safety and effectiveness to the legally marketed predicate device.