



Food and Drug Administration
10903 New Hampshire Avenue
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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

November 19, 2015

Re: K153101
Trade/Device Name: BladderScan[®] Prime System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: November 6, 2015
Received: November 9, 2015

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 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 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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style and is positioned above the typed name.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153101

Device Name

BladderScan® Prime system

Indications for Use (Describe)

The BladderScan® Prime system is an ultrasound device intended to be used for measuring the urine volume in 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Diagnostic Ultrasound Indications for Use Form

System: BladderScan® Prime 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	N						
	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 (Specify)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Bladder)	N						

N = new indication; P = previously cleared; 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

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 System

Transducer: 2.49/1.72 MHz Harmonic Transducer

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	N						
	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 (Specify)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Bladder)	N						

N = new indication; P = previously cleared; 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

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: October 2, 2015

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

Verathon Inc.
 20001 North Creek Parkway
 Bothell, WA 98011

Corresponding Official:

Rhonda M. Kops, RAC
 Manager, Regulatory Affairs

Phone: 425-867-1348 ext. 5643

Fax: 425-883-2896

Email: rhonda.kops@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 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® BVI 9400 K071217

4. Device Description:

The BladderScan® Prime system instrument provides noninvasive measurement of urinary bladder volume. The instrument calculates the bladder volume using patented NeuralHarmonics® technology, which is easy to use and comfortable for the patient. Volume measurements made with NeuralHarmonics® are accurate than those from conventional two-dimensional ultrasound as they are based on a more complex, three-dimensional image of the bladder.

Bladder volume, mode (male, female and small child), directional aiming with real-time feedback, battery status and usage rate indicators are displayed on the LCD display. The system also includes a battery charger for custom, user-replaceable lithium-ion batteries included with the system,

5. Intended Use:

The BladderScan® Prime system is an ultrasound device intended to be used for measuring the urine volume in the bladder non-invasively.

Clinical Application: Abdominal B-Mode (Bladder)

6. Technological Characteristics:

The BladderScan® Prime system and BladderScan® BVI 9400 system are both Track 1 devices that employ the same fundamental technology. The comparison table is provided below.

Comparison Category	Proposed BladderScan® Prime (Verathon Inc.)	Predicate BladderScan® BVI 9400 (Verathon Inc.)
Comparison Overview		
FDA 510(k) Number		K071217
FDA Ultrasound Guidance Track	Track 1	Track 1
Device Classification Name	System, Imaging, Pulsed Echo, Ultrasonic	System, Imaging, Pulsed Echo, Ultrasonic

Intended Use/Indications For Use	The BladderScan Prime system is an ultrasound device intended to be used for measuring the urine volume in the bladder non-invasively.	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.
Contraindications	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.	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.
Patient/User Characteristics		
Target Population	Male, Female, and Pediatric patients	Male, Female, and Pediatric patients
Anatomical Site	Bladder	Bladder
Users	Physicians/Medical Professionals	Physicians/Medical Professionals
Technological Characteristics and Performance		
Patient Contact Material	Lexan Polycarbonate Plastic HP1-1H112 (colorant: PCM 84907 Dark Gray 424C)	Low Density Polyethylene Plastic (LDPE) Dow 955i (colorant: Techmer PM 84149 Cool Grey 4C)
Sterility	non-sterile	non-sterile
Power Source	electrical (lithium-ion battery)	electrical (lithium-ion battery)
Energy Delivered	ultrasound	ultrasound
Measurement Accuracy	± 15% ± 15ml	± 15% ± 15ml
Measurement Range	0 to 999 mL	0 to 999 mL
Variable Acoustic Output Settings	No	No
Controls to Change Acoustic Output During Scan	No	No

Modes of Operation	B -mode	B-mode
Transducer Type	Mechanical Sector Probe	Mechanical Sector Probe
Transducer Diameter	13 mm	13 mm
Number of Elements	1	1
Transducer Resonant Frequency	2.95 MHz	2.95 MHz
Nominal Acoustic Output Frequencies	2.49 / 1.72 MHz	3.0 / 1.74 MHz
Sector Angle	120 degrees	120 degrees
Number of Scan Plans	12	12
Design and Usability Features		
Portable	Yes	Yes
Display	LCD	LCD
Scan Button	Yes	Yes
Touchscreen Operation	Yes	No
Selectable Unit Orientation (Patient Right/Left)	Yes	No
Live Scan Image	Yes	No
Data Connections	USB, SD card	Wireless
Attached Printer	Yes	Yes
Computer Software	No	Yes (ScanPoint)
Accessories	Printer, battery, battery charger, power cord, mobile cart	ultrasound gel, battery, battery charger, power cord, calibration tank, mobile cart
Safety Standards		
Acoustic Output: Maximum Mechanical Index (MI)	0.42	0.95
Acoustic Output: Maximum Thermal Index (TI)	≤ 1.0	≤ 1.0
Acoustic Output: Intensity, Spatial Peak Temporal Average (I_{SPTA})	≤ 1.0 mW/cm ²	≤ 1.0 mW/cm ²
Acoustic Output: Intensity, Spatial Peak Pulse Average (I_{SPPA})	≤ 12.0 W/cm ²	≤ 10.0 W/cm ²
Biocompatibility Standard Compliance	ANSI/AAMI/ISO 10993-1:2009, ANSI/AAMI/ ISO 10993-5:2009, ISO 10993-10:2010, ANSI/AAMI/ISO 10993-12:2012	ISO 10993-1:2009

Electrical Safety Standard Compliance	IEC 60601-1:2005, IEC 60601-2-37:2007	IEC 60601-1:2005, IEC 60601-2-37:2007
Electromagnetic Compatibility Standard Compliance	IEC 60601-1-2: 2007	IEC 60601-1-2: 2007

7. Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The BladderScan® Prime 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 system is designed to comply with the following standards.

FDA Consensus Standards

Reference No.	Title
ANSI/ISO 10993-1:2009	Biological evaluation of medical devices. Part 1: Evaluation and testing
ANSI/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.
ANSI/AAMI/ISO 10993-12:2012	Biological evaluation of medical devices. Part 12: Sample preparation and reference materials.
IEC 60601-1:2005	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 basic safety and essential performance-Collateral standard-Electromagnetic compatibility-Requirements and tests.
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.
ALUM/NEMA UD-2:2004	Standard for real time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment.
ALUM AOMS:2004	Acoustic output measurement standard for diagnostic ultrasound equipment.

Miscellaneous Standards

Reference No.	Title
IEC 60601-1-6:2005	Medical device equipment. Part 1-6: General requirements for basic safety and essential performance-Collateral standard usability.
AAMI HE75:2009	Human Factors Engineering- design of medical devices
AAMI/IEC 62366:2007	Medical Devices, Part 1: Application of usability engineering to medical devices.
ISO 14971:2012	Medical Devices-Application of risk management to medical devices.
IEC 60950-1	Information technology equipment- Safety. Part 1: General requirements.
ISO 13485:2003	Medical devices- Quality management systems-requirements for regulatory purposes

8. Conclusion

The intended use and other key features are consistent with traditional practice and FDA guidance. The BladderScan[®] Prime system and the predicate device conform to applicable electromedical device safety standards with compliance verified through independent evaluation. The BladderScan[®] Prime 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 system is substantially equivalent with regard to safety and effectiveness to the legally marketed device.