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510(K) SUMMARY
(As required by 21 CFR 807.92(a))

DEC 0 1 2008

A. Submitter Information

Company: Verathon Inc.
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Bothell, WA 98011
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Contact: Richard A. Zeine
Director of Quality Assurance and
Regulatory Affairs
Date: August 15, 20008

B. Device Information

Trade/Proprietary Name: Verathon Inc. BladderScan® BVI 9600 Ultrasound System with AortaScan®

Common Name: Diagnostic Ultrasound System with Accessories

Classification Name(s):

Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology
Ultrasonic Pulsed Echo Imaging System
- FR Classification 892.1560
- Product Code 90-IYO

Diagnostic Ultrasound Transducer
- FR Classification 892.1570
- Product Code 90-ITX

Predicate Device: Verathon BladderScan® BVI 9400 Ultrasound System (K071217)
And
SonoSite MicroMaxx High-Resolution Ultrasound System (C3 Series)
(K053069)

Device Description: The BVI9600, with AortaScan®, is a B-mode ultrasonic instrument that is portable and battery operated. The BVI 9600 has two user controlled modes of operation; (1) - Bladder Volume Measurement and (2)- Abdominal Aortic Measurement, both noninvasive. Either bladder volume or aortic diameter measurement functions can be chosen by a button press. When the scan button is pressed the BVI9600 uses patented Vmode® technology to measure ultrasonic

		reflections on multiple planes inside the body to produce a 3-dimensional image. Based on these images and the mode of operation chosen, the BVI9600 either calculates and displays the bladder volume (BladderScan® mode) or calculates and displays the abdominal aortic diameter (AortaScan® mode). The measurements made with Vmode ultrasound are more accurate than those from conventional 2-dimensional ultrasound, as they are based on a more complex, 3-D image. Bladder volume (in BladderScan® mode), aortic diameter (in AortaScan® mode), mode selection, directional aiming, battery status, and usage rate indicators are all displayed on the BVI9600 LCD display. The instrument contains a thermal printer that allows the user to print exams with a single button click.
	Intended Use:	New device: The Verathon Inc. BladderScan® BVI 9600 with AortaScan® is a user selectable dual function ultrasound device that projects ultrasound energy either into the lower abdomen to obtain an image of the bladder for measuring bladder volume or the mid abdomen to obtain an image of the abdominal aorta for aortic diameter measurement.
	Contraindications (U.S. Only):	The BladderScan® BVI 9600 is not intended for fetal use or use on pregnant patients. The BladderScan® BVI 9600 is not intended for acute events such as aortic dissection, ulcer or rupture.
C.	Comparison of Required Technological Characteristics:	The Verathon Inc. BladderScan® BVI 9600 Ultrasound System with AortaScan® retains the same bladder volume measurement features of the Verathon inc. BladderScan® BVI 9400 System (K071217). The BVI 9600 is identical to the BVI 9400, with regards to hardware, software, transducer and calibration method. The Verathon Inc. BladderScan® BVI 9600, with AortaScan®, and its integrated 3.0 MHz mechanical sector transducer operate only in B-mode to locate and automatically measure bladder volume (in BladderScan® Mode) or abdominal aortic diameter (in AortaScan® Mode). The same transducer is driven at 1.74 MHz to obtain a second harmonic for enhanced bladder wall detection. Bladder volume (in BladderScan® Mode), aortic diameter (in AortaScan® Mode), patient gender, non optimal directional aiming, battery status, and usage rate indicators are all displayed on the Verathon Inc. BladderScan® BVI 9600 Ultrasound System scanner. The ultrasonic power transmitted from the system is not user adjustable. The portable Verathon Inc. BladderScan® BVI 9600 Ultrasound System with AortaScan® is applied to the

patient's abdomen along with Sontac Ultrasound Coupling Gel to obtain aortic measurement. The BladderScan® BVI 9600 Ultrasound System transducer collects cross- sectional images of the bladder or aorta from twelve (12) scan planes. From this information, the Verathon Inc. BladderScan® BVI 9600 Ultrasound System constructs a finite element model of the bladder (in BladderScan® Mode) or aorta (in AortaScan® Mode) and automatically computes the volume of urine via volumetric integration (for the bladder measurement) or the diameter of the aorta (for aortic measurement), depending on the mode of operation chosen (AortaScan® or BladderScan®).

In order to demonstrate the BladderScan® accuracy claimed in 0270-0422 -xx-55, two third party vendors were contracted to build tissue equivalent phantoms with known dimensions. The supplier of the aortic phantom, Blue Phantom, is known for supplying medical imaging phantoms to the medical marketplace as is the manufacturer of the bladder phantom, Computer Imaging Reference Systems (CIRS).

The AortaScan® phantom is essentially a tube roughly the length of an adult aorta, with a bulge in the length of the tube that represents an aortic aneurism, filled with blood mimicking material that is surrounded by tissue mimicking material. Known diameters of the tube can then be compared to the AortaScan® measurements from the BVI 9600.

The BladderScan® Phantom is essentially a balloon which gets filled with urine mimicking material and then the filled balloon is surrounded with tissue mimicking material. This balloon is a known volume and can be compared to the BladderScan® measurements from the BVI 9600.

During the manufacturing processes, both Blue Phantom and CIRS measure key parameters of the physical parts as the parts are constructed. These measurements are all NIST traceable and each phantom comes with a certification sheet listing the measurements.

These results obtained through the Verathon Inc. BladderScan® BVI 9600 Ultrasound System are compared to the expected results derived from the NIST traceable measurements. In addition to these measurements, additional measurements are taken by standard ultrasound systems, such as the Sonosite 180, to compare bladder volume measurements and aortic measurements.

AortaScan® accuracy has been demonstrated by comparing the AortaScan® Phantom measurements to the measurements of the Verathon Inc. BladderScan® BVI 9600 Ultrasound System.

		The calibration system for the Verathon Inc. BladderScan® BVI 9600 Ultrasound System with AortaScan® is exactly the same as the Verathon Inc. BladderScan® BVI 9600 Ultrasound System (K071217).
D.	Summary and Conclusion of Non Clinical and Clinical Testing	Design and testing of the Verathon Inc. BladderScan® BVI 9600 Ultrasound System with AortaScan® indicates that the BVI 9600 is substantially equivalent to the Verathon Inc. BladderScan® BVI 9400 Ultrasound System (K071217) for bladder volume measurements and equivalent to the Sonosite MicroMaxx Ultrasound System (K053069)for aorta scan measurements. All acoustic output measurements for the BladderScan® BVI 9600 Ultrasound System with AortaScan® are not changed from the BladderScan® BVI 9400 Ultrasound System and remain within Pre-amendment limits.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Richard A. Zeine
Director of Quality and Regulatory Affairs
Verathon Incorporated
20001 North Creek Parkway
BOTHELL WA 98011

DEC 0 1 2008

Re: K082456
Trade/Device Name: Verathon Inc. BladderScan® BVI 9600 with AortaScan Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: October 7, 2008
Received: October 8, 2008

Dear Mr. Zeine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the Verathon Inc. BladderScan® BVI 9600 with AortaScan Ultrasound System, as described in your premarket notification:

Transducer Model Number3.0/1.74 MHz Second Harmonic Transducer

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K082456

Device Name: Verathon Inc. BladderScan® BVI 9600 with AortaScan® Ultrasound System

Indications for Use:

- Abdomen, B-Mode, per Indications for Use Ultrasound Form
- The Verathon Inc. BladderScan® BVI 9600 with AortaScan® Mode is a user selectable, dual-function ultrasound device that projects ultrasound energy either into the lower abdomen to obtain an image of the bladder for measuring bladder volume, or into the mid-abdomen to obtain an image of the abdominal aorta for aortic diameter measurement.

Contraindications:

- The BladderScan® BVI9600 is contraindicated for fetal use and for use on pregnant patients.

The BladderScan® BVI 9600 is not intended for acute events such as aortic dissection, ulcer or rupture.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K082456

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: BladderScan® BVI 9600 Ultrasound System

3.0 / 1.74 MHz Second Harmonic Transducer

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

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P						
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicles)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (Abdominal Aorta Measurement)	N						
	Peripheral vessel							
	Other (Bladder)	P						

N= new indication; P= previously cleared by FDA (K071217)

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K082456