K072517

SEP 26 2007

510(k) Summary of Safety and Effectiveness

Boston Scientific Corporation

iLab™ Ultrasound Imaging System

Submitted By

Boston Scientific Corporation
49700 Bayside Parkway
Fremont, CA 94538

Contact Person

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Principal Regulatory Affairs Specialist
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Date Prepared

September 06, 2007

Proprietary Name

iLab™ Ultrasound Imaging System

Common Name(s)

Ultrasound Diagnostic Imaging System
Ultrasonic Pulsed Doppler Imaging System (90IYN)
Ultrasonic Pulsed Echo Imaging System (90IYO)

Classification Name(s)

21 CFR Part 892.1550 (90IYN)
Ultrasonic Pulsed Doppler Imaging System
21 CFR Part 892.1560 (90IYO)
Ultrasonic Pulsed Echo Imaging System

Predicate Device The iLab™ Ultrasound Imaging System with software version 1.3 Update and the Integrated Installation Configuration Option is substantially equivalent to the following device:

Product	510(k)	Clearance Date
iLab™ Intravascular Ultrasound System	K051579	July 14, 2005

Description of the Device

The iLab™ Ultrasound Imaging System is designed for real-time viewing of intravascular anatomies and is intended to be a basic diagnostic tool for imaging and evaluation of patients who are candidates for transluminal procedures.

The iLab™ System consists of two compact PC units (one for Image Processing and one for Data Acquisition), up to two displays (one primary and an optional secondary). The iLab System imaging and processing PC are used during an intravascular procedure, at the end of the IVUS procedure, the processing PC supports the archiving of the images obtained during the procedure. The iLab System processing PC converts the native iLab images into DICOM format images prior to archiving to removal media such as a CD, DVD or removable hard disk cartridge. Images can also be archived to a DICOM network server.

The iLab™ System is available in two configurations: a Cart-based Configuration and an Installed Configuration. There is no functional or electrical difference between the Cart-Based and Installed Configurations; differences are limited to cable lengths and the location of the modules of the system. The main market features of the iLab System are as follows:

Cart System

The Cart based system contains the complete iLab System in a portable, compact cart. The Cart System supports one LCD monitor.

Installed System

Multiple monitor mounting options for installation into the Hospital's catheter lab procedure room

Tableside Controller

Provides sterile field control of IVUS measurements and playback of IVUS runs

Touch Panel

Intuitive user interface and simplified display

Upgradeable

The iLab system allows for future innovation and technological advancement

The proposed new Integrated Installation Configuration Options supports an additional installed version configuration to enable the use of a customer's existing catherization lab monitor as the second monitor.

Intended Use / Indications for Use

The iLab™ Ultrasound Imaging System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.

Device Technology Characteristics and Comparison to Predicate Device

The iLab™ System applies ultrasound energy through a transducer enclosed within a catheter. This ultrasound energy is directed from the catheter in the lumen of a vessel into the interior vessel wall of the patient in order to obtain a two-dimensional image of the vessel anatomy. The two-dimensional image, reconstructed from the reflected RF Ultrasound echo, can be used to evaluate the morphology of the vessel and as such potentially detect abnormalities or obstructions. Each of the technological characteristics found in the iLab™ System 1.3 Update are identical or similar to those of the predicate device, iLab Intravascular Imaging System,

Non-Clinical Testing

Bench electrical safety and acoustic output safety testing demonstrated that thecurrently marketed iLab™ System, and its accessories met or exceeded performance requirements and is safe and effective for its intended use.

The Integrated Installation Configuration Option was evaluated by an outside testing agency for the iLab System and it was determined that no new external testing for EMC was required.

All software risk mitigations determined by the FMEA have been verified to be effective and demonstrate that the iLab 1.3 Update meets all product and marketing requirements.

Software Verification Testing

Software unit and system level verification testing demonstrate that the 1.3 Update meets the acceptance criteria as noted in the iLab System Software Unit and System Test Plans. All requirements in the Software Requirements Specifications have been verified by the system level testing.

The iLab System 1.3 Update has been fully verified in accordance with applicable FDA guidance documents. This testing includes software verification testing performed on multiple configurations of PC systems. The results demonstrate that iLab System 1.3 Update satisfies all Product and Marketing requirements for its intended purpose as a safe and effective update to the predicate iLab System.

Software Validation Testing

The iLab System 1.3 Update validation effort will be performed by testers with iLab clinical experience on PC systems that are production equivalent and meet the minimum system requirements. The validation results summary report in progress at the time of this submission. All plans, test results and summary reports will be retained in the Design History File for the iLab System 1.3 Update project.

Hardware Verification Testing

The iLab Integrated Installation Configuration Option contains minimal hardware necessary to send the video signal to the customer's LCD Monitor. The video interface requirements have been defined, verified and validated to support specified imaging medical device vendors. An additional on-site validation on 3 or more customer sites who utilize Angiography systems from these vendors will ensure that the video interface is robust. The use of industry standard Information Technology Equipment (ITE) certified video converters (also called multi-modality switches), cabling and monitors provides a broad based video interface for ease in interconnectivity.

All hardware risk mitigations determined by the FMEA have been verified to be effective and demonstrate that the iLab Integrated Installation Configuration Option meets all product and marketing requirements.

On-Site Validation Testing

The on-site validation for the video connections is intended to ensure customer acceptance of the image quality with the current iLab imaging system when using external video monitors that meet the video interface requirements. The on-site validation effort is in progress at the time of this submission.

All plans, test results and summary reports will be retained in the Design History File for the iLab System Integrated Installation Configuration Option project.

Conclusion

The iLab™ Ultrasound Imaging System with the 1.3 Update and the Integrated Installation Configuration Option, contains the same fundamental technology, has similar technical

characteristics (i.e. GUI and software functions) and has the same intended use as the predicate device, the iLab™ Ultrasound Imaging System.

Based on the non-clinical and design verification tests results, the subject device has been shown to be substantially equivalent to the currently marketed device and safe and effective for its intended use..

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Christine Dunbar
Principal Regulatory Affairs Specialist
Boston Scientific Corporation
47900 Bayside Parkway
FREMONT CA 94538

SEP 26 2007

Re: K072517
Trade/Device Name: iLab™ Ultrasound Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX and IYO
Dated: September 6, 2006
Received: September 7, 2007

Dear Ms. Dunbar:

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 iLab™ Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

Sonicath® Ultra™, 6F 20 MHz
Sonicath® Ultra™, 9F 9 MHz
Sonicath® Ultra™, 6F 12.5 MHz
Sonicath® Ultra™, 3.2F 20 MHz
Ultra ICE, 9F 9 MHz
Atlanits® SR, 3.2F 40 MHz
Atlantis® PV, 8F 15 MHz
Atlantis® SR Pro, 3.2F 40 MHz
Atlantis® ICE, 9F 9 MHz
Atlantis® SR Pro^2, 3.2F 40 MHz
iSight, 2.4F 40 MHz

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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use Statement

510(k) Number:

Device Name: iLab™ Ultrasound Imaging System

Indications for Use: The iLab™ Ultrasound Imaging System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.

Prescription Use __X__ AND/ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072517

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072517

Diagnostic Indications for Use Form for the iLab™ Ultrasound Imaging System

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular		P								
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = New indication; P = Previously cleared by FDA; E = Added under Appendix E

Additional Comments: Cleared July 14, 2005, K051679

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Table 5-2: Track 1 Summary Table for the iLab™ Ultrasound Imaging System

Clinical Application	A	B	M	PWD	CWD	CD	Combined (specify)	Other† (specify)
Ophthalmic								
Fetal Imaging & Other*		X						
Cardiac, Adult & Pediatric								
Peripheral Vessel								

*Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-skeletal (conventional), Musculo-skeletal (superficial)

† Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072517

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Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072517

Diagnostic Indications for Use Form
for the
Sonicath® Ultra™, 6F 20 MHz

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular		P								
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = New indication; P = Previously cleared by FDA; E = Added under Appendix E

Additional Comments: Cleared under K890772, May 10, 1989 and K060947 (cleared April 19, 2006)

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510(k) Number K072517

Table 5-2: Track 1 Summary Table for the Sonicath® Ultra™, 6F 20 MHz

Clinical Application	A	B	M	PWD	CWD	CD	Combined (specify)	Other† (specify)
Ophthalmic								
Fetal Imaging & Other*		X						
Cardiac, Adult & Pediatric								
Peripheral Vessel								

*Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-skeletal (conventional), Musculo-skeletal (superficial)

† Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

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Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072517

Diagnostic Indications for Use Form
for the
Sonicath® Ultra™, 9F 9 MHz

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular		E								
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = New indication; P = Previously cleared by FDA; E = Added under Appendix E
Additional Comments: Released to market February 28, 1996 via Letter-To-File against K902245 (cleared October 9, 1996).

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Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072517

Table 5-2: Track 1 Summary Table for the Sonicath® Ultra™, 9F 9 MHz

Clinical Application	A	B	M	PWD	CWD	CD	Combined (specify)	Other† (specify)
Ophthalmic								
Fetal Imaging & Other*		X						
Cardiac, Adult & Pediatric								
Peripheral Vessel								

*Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-skeletal (conventional), Musculo-skeletal (superficial)

† Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

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Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072517

Diagnostic Indications for Use Form
for the
Sonicath® Ultra™, 6F 12.5 MHz

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular		E								
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = New indication; P = Previously cleared by FDA; E = Added under Appendix E
Additional Comments: Released to market February 28, 1997 via Letter-To-File against K902245 (Cleared October 9, 1996).

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510(k) Number K072517

Table 5-2: Track 1 Summary Table for the Sonicath® Ultra™, 6F 12.5 MHz

Clinical Application	A	B	M	PWD	CWD	CD	Combined (specify)	Other† (specify)
Ophthalmic								
Fetal Imaging & Other*		X						
Cardiac, Adult & Pediatric								
Peripheral Vessel								

Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-skeletal (conventional), Musculo-skeletal (superficial)

† Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

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Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072517

Diagnostic Indications for Use Form
for the
Sonicath® Ultra™, 3.2F 20 MHz

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular		P								
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = New indication; P = Previously cleared by FDA; E = Added under Appendix E

Additional Comments: Cleared under K970049, June 20, 1997.

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510(k) Number K072517

Table 5-2: Track 1 Summary Table for the Sonicath® Ultra™, 3.2F 20 MHz

Clinical Application	A	B	M	PWD	CWD	CD	Combined (specify)	Other† (specify)
Ophthalmic								
Fetal Imaging & Other*		X						
Cardiac, Adult & Pediatric								
Peripheral Vessel								

Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-skeletal (conventional), Musculo-skeletal (superficial)

† Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

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Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072517

Diagnostic Indications for Use Form
for the
Ultra ICE, 9F 9 MHz

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

Clinical Application	Mode of Operation: A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular		E								
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = New indication; P = Previously cleared by FDA; E = Added under Appendix E

Additional Comments: Released to market December 10, 1997 via Letter-To-File against K902245 (Cleared October 9, 1996).

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510(k) Number K012617

Table 5-2: Track 1 Summary Table for the Ultra ICE, 9F 9 MHz

Clinical Application	A	B	M	PWD	CWD	CD	Combined (specify)	Other† (specify)
Ophthalmic								
Fetal Imaging & Other*		X						
Cardiac, Adult & Pediatric								
Peripheral Vessel								

Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-skeletal (conventional), Musculo-skeletal (superficial)

† **Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging**

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072517

Diagnostic Indications for Use Form
for the
Atlantis® SR, 3.2F 40 MHz

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular		P								
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = New indication; P = Previously cleared by FDA; E = Added under Appendix E
Additional Comments: Cleared under K000743, September 7, 2000.

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Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072517

Table 5-2: Track 1 Summary Table for the Atlantis® SR, 3.2F 40 MHz

Clinical Application	A	B	M	PWD	CWD	CD	Combined (specify)	Other† (specify)
Ophthalmic								
Fetal Imaging & Other*		X						
Cardiac, Adult & Pediatric								
Peripheral Vessel								

Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-skeletal (conventional), Musculo-skeletal (superficial)

† Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072517

Diagnostic Indications for Use Form
for the
Atlantis® PV, 8F 15 MHz

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular		P								
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = New indication; P = Previously cleared by FDA; E = Added under Appendix E

Additional Comments: Cleared under K022860, November 21, 2002 and K041727 (cleared July 23, 2004) and K050684 (cleared May 20, 2005)

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Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072517

Table 5-2: Track 1 Summary Table
for the
Atlantis® PV, 8F 15 MHz

Clinical Application	A	B	M	PWD	CWD	CD	Combined (specify)	Other† (specify)
Ophthalmic								
Fetal Imaging & Other*		X						
Cardiac, Adult & Pediatric								
Peripheral Vessel								

Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-skeletal (conventional), Musculo-skeletal (superficial)

† Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072517

Diagnostic Indications for Use Form
for the
Atlantis® SR Pro, 3.2F 40 MHz

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular		E								
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = New indication; P = Previously cleared by FDA; E = Added under Appendix E

Additional Comments: Released to market February 14, 2003 via Letter-To-File against K000743 (Cleared September 7, 2000) and K010707 (Cleared March 28, 2001) and K063312 (cleared November 30, 2006)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072517

Table 5-2: Track 1 Summary Table for the Atlantis® SR Pro, 3.2F 40 MHz

Clinical Application	A	B	M	PWD	CWD	CD	Combined (specify)	Other† (specify)
Ophthalmic								
Fetal Imaging & Other*		X						
Cardiac, Adult & Pediatric								
Peripheral Vessel								

Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-skeletal (conventional), Musculo-skeletal (superficial)

† Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072517

Diagnostic Indications for Use Form
for the
Atlantis® ICE, 9F 9 MHz

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular		E								
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = New indication; P = Previously cleared by FDA; E = Added under Appendix E

Additional Comments: Released to market August 8, 2003 via Letter-To-File against K902245 (Cleared October 9,1996).

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510(k) Number K072517

Table 5-2: Track 1 Summary Table for the Atlantis® ICE, 9F 9 MHz

Clinical Application	A	B	M	PWD	CWD	CD	Combined (specify)	Other† (specify)
Ophthalmic								
Fetal Imaging & Other*		X						
Cardiac, Adult & Pediatric								
Peripheral Vessel								

Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-skeletal (conventional), Musculo-skeletal (superficial)

† Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072517

Diagnostic Indications for Use Form
for the
Atlantis® SR Pro^2, 3.2F 40 MHz

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular		P								
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = New indication; P = Previously cleared by FDA; E = Added under Appendix E

Additional Comments: Cleared under K050577, March 30, 2005 and K063312 (cleared November 30, 2006)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K073517

Table 5-2: Track 1 Summary Table
for the
Atlantis® SR Pro^2, 3.2F 40 MHz

Clinical Application	A	B	M	PWD	CWD	CD	Combined (specify)	Other† (specify)
Ophthalmic								
Fetal Imaging & Other*		X						
Cardiac, Adult & Pediatric								
Peripheral Vessel								

Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-skeletal (conventional), Musculo-skeletal (superficial)

† Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073517

Diagnostic Indications for Use Form for the iSight, 2.4F 40 MHz

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular		P								
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = New indication; P = Previously cleared by FDA; E = Added under Appendix E

Additional Comments: Cleared under K060175, March 24, 2006.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Number K072517

Table 5-2: Track 1 Summary Table for the Atlantis® SR Pro^2, 3.2F 40 MHz

Clinical Application	A	B	M	PWD	CWD	CD	Combined (specify)	Other† (specify)
Ophthalmic								
Fetal Imaging & Other*		X						
Cardiac, Adult & Pediatric								
Peripheral Vessel								

Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-skeletal (conventional), Musculo-skeletal (superficial)

† Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging