

Intended Use:

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

Comparison To Predicate Devices:

The Galaxy Imaging System applies reflected ultrasound energy through a catheter tip transducer directly into the interior vessel wall of the patient to obtain a two dimension image of the vessel structure that can be used to detect abnormalities or obstructions. There are other ultrasound systems presently on the market with these intravascular imaging capabilities. The subject BSC Galaxy Imaging System is similar in design, function, and application to these ultrasound systems.

The Galaxy Imaging System is substantially equivalent in intended use, design and operation characteristics to the following devices: (1) BSC (formerly CVIS) Insight III Imaging System (K921750) (with Automatic Pullback Device (K933517) and LongView (K930311)), and (2) EndoSonics In-Vision™ (Clearance number: Not available). All predicate devices are used for ultrasound imaging of intravascular pathology in vessel anatomy.

Non-Clinical Tests:

Bench and acoustic output testing will be tested to demonstrate that the BSC Galaxy Intravascular Ultrasound Imaging System is safe and effective, while meeting the anticipated clinical requirements for its intended use.

Bench Testing:

Bench testing, both hardware and software will undergo complete verification and validation testing.

Acoustic Output Testing:

The BSC Galaxy Intravascular Ultrasound Imaging System will be measured and calculated per the *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment (UD-2, Revision 1, December 7, 1993)*, not 1997, as referenced in the FDA guidance *Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* of September 30, 1997. This is a possible deviation of the acoustic output measurement methodology at Boston Scientific from the NEMA guidance documents referred to in the FDA's guidance document.

Rationale for Deviation

The FDA guidance document *Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* of September 30, 1997 refers to the *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment (NEMA 1997)*, and specifically to its Section 3.3.2. However, it is our understanding that no 1997 standard has been published yet, and the most recent version of the NEMA standard that we have been able to obtain is the *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment (UD-2, Revision 1, December 7, 1993)*. The section 3.2.2 of this document does not reflect the wording of the 1997 FDA document and its reference to the 1997 NEMA standard regarding the low end of the frequency response of the hydrophone system (i.e., $f_c/20$). Also, the 1997 FDA guidance document states the following: "*non-membrane (e.g., needle-type) hydrophones are acceptable for uses not directly affecting reporting or labeling, such as in quality control measurements*" which is not reflected in the wording of the Section 3.2.2 in the *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment (UD-2, Revision 1, December 7, 1993)*.

Summary:

There are other ultrasound systems presently on the market with intravascular imaging capabilities. The subject BSC Galaxy Imaging System is similar in design, function, and application to these ultrasound systems and is substantially equivalent to these currently marketed predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 1998

Donna Templeman
Boston Scientific Corporation
2710 Orchard Parkway
San Jose, CA 95134

Re: K980851
Galaxy Intravascular Ultrasound Imaging System
Dated: March 4, 1998
Received: March 5, 1998
Regulatory class: II
21 CFR 892.1560/Procode: 90 IYO

Dear Ms. Templeman:

We have reviewed your section 510(k) 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 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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Galaxy Intravascular Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

Sonicath Ultra	9	MHz
Discovery 2.6F	40	MHz
Discovery 2.6F	30	MHz
Sonicath Ultra 3.2F	20	MHz
Sonicath Ultra 6F	20	MHz
Sonicath Ultra 6F	12.5	MHz
UltraCross 2.9F	30	MHz
UltraCross 3.2F	30	MHz

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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:

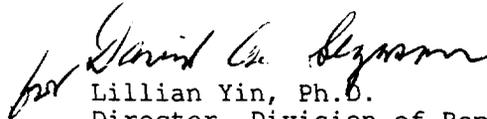
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

If you have any questions regarding the content of this letter, please contact Paul Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 980851

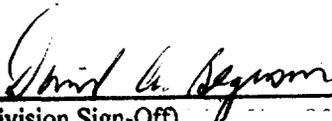
Device Name: Galaxy Intravascular Ultrasound Imaging System

Indication For Use:

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)


David A. Bergson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980851

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

K 980851

**Diagnostic Ultrasound Indications for Use Form
For
Galaxy System Imaging Console**

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or 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		N								
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: _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



**Diagnostic Ultrasound Indications for Use Form
For
Sonicath Ultra 9F/9MHz**

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or 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)										

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K980851

Diagnostic Ultrasound Indications for Use Form
For
Discovery 2.6F/40MHz

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or 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)										

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K980851

Diagnostic Ultrasound Indications for Use Form
For
Discovery 2.6F/30MHz

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or 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)										

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K980851

Special 510(k)
Galaxy Intravascular Ultrasound Imaging System

Diagnostic Ultrasound Indications for Use Form
For
Sonicath Ultra 3.2F/20MHz

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or 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)										

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K980851

**Diagnostic Ultrasound Indications for Use Form
For
Sonicath Ultra 6F/20MHz**

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or 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)										

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K980851

Diagnostic Ultrasound Indications for Use Form
For
Sonicath Ultra 6F/12.5MHz

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or 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)										

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K980851

Diagnostic Ultrasound Indications for Use Form
For
UltraCross 2.9F/30MHz

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or 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)										

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K980851

Special 510(k)
Galaxy Intravascular Ultrasound Imaging System

Diagnostic Ultrasound Indications for Use Form
For
UltraCross 3.2F/30MHz

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or 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)										

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