K99263/

DEC 15 1999

510(k) Summary

Sponsor:

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or

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Hogan & Hartson, LLP
555 Thirteenth Street, N.W.
Washington, DC 20004
Tel: (202) 637-5813
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Submission Date:

August 5, 1999

Device Name:

AcuNav™ Diagnostic Ultrasound Catheter

Classification:

Diagnostic intravascular catheters and ultrasonic transducers--class II (21 C.F.R. §§ 870.1200 and 892.1570)

Predicate Devices:

1. Boston Scientific Corporation's Sonicath Ultra™ Imaging Catheter (9 Fr/ 9 MHz) (K970049), (used in conjunction with EP Technologies' Galaxy Intravascular Ultrasound Imaging System (K980851))

2. Cardiovascular Imaging Systems' (CVIS) Insight Catheter for Intracardiac Use (10 Fr) (K921148).

Device Description:

The AcuNav is an ultrasound-tipped catheter device which is used directly within the vasculature and/or the right heart for intravascular or intracardiac ultrasound imaging. The AcuNav incorporates a single-use, disposable ultrasonic phased-array imaging transducer, which must be used in conjunction with an Acuson ultrasound imaging platform to generate the acoustic waves and process the information for display to the physician. The catheter is 10 French in diameter and 90 cm in insertable length. The distal portion of the catheter can be deflected in four directions in two orthogonal planes: left-right (in a plane perpendicular to the image plane) and anterior-posterior (in a plane coincident with the image plane). The distal end of the catheter contains the transducer, which is oriented to provide a two-dimensional (90 degree vector) image in a plane parallel to the axis of the catheter. The transducer offers all imaging modes at frequencies between 4.0 and 10.0 MHz.

Intended Use:

For use directly within the vasculature and/or the right heart for intravascular or intracardiac ultrasound imaging. The device is specifically indicated for use in visualization of vascular anatomy, cardiac and great vessel anatomy and physiology, or other devices in the heart, as well as measurement of blood flow. The company anticipates that the device will be used for a variety of intravascular and intracardiac imaging applications, consistent with its intended use, including vascular stent placement, monitoring left ventricular function post-surgery; identifying congenital abnormalities before therapeutic procedures; visualizing the relative orientation of diagnostic and therapeutic catheters; and visualizing procedures such as transseptal insertions of other catheters, valvuloplasties, balloon septostomies, septal defect closures, and pacemaker or defibrillator lead insertion or extraction.

Substantial Equivalence:

Acuson's AcuNav Catheter and the predicate devices have the same intended use and very similar principles of operation and technological characteristics. All of the devices are intended for use in intravascular and/or intracardiac imaging. The minor technological differences between the AcuNav Catheter and the predicate devices, *i.e.,* in acoustic parameters, transducer configuration, imaging format, steering mechanism, materials, or

sterilization methods, do not raise any new questions of safety or effectiveness, as confirmed by performance testing, animal testing, and human clinical testing. The AcuNav Catheter also has been demonstrated to be biocompatible and non-pyrogenic. Therefore, Acuson's AcuNav Catheter is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 8 2001

Acuson Corporation
c/o Mr. Howard M. Holstein
Hogan and Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, N.W.
Washington, D.C. 20004

Re: K992631
Trade Name: AcuNav Diagnostic Ultrasound Catheter
Regulation Number: 21 CFR 870.1200 and 892.1570
Regulation Name: Intravascular Diagnostic Catheter
Diagnostic Ultrasound Transducer
Regulatory Class: II (two)
Product Code: DQO and ITW
Dated: November 12, 1999
Received: November 12, 1999

Dear Mr. Holstein:

This letter corrects our substantially equivalent letter of December 15, 1999, regarding the indications for use.

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). 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.

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); 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 continue marketing your device as described in your Section 510(k) 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 the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Diagnostic Ultrasound Indications for Use Form
For
AcuNav™ Diagnostic Ultrasound System

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

Clinical Applications	A	B	M	PWD	CWD	Color Doppler	Power (Ampl.) Doppler	Combined (Specify)	Other Harmonic Imaging
Ophthalmic									
Fetal		P	P	P	P	P	P	*P	P
Abdominal		P	P	P	P	P	P	*P	P
Intra-operative (vascular)		P	P	P	P	P	P	*P	P
Intra-operative Neurological									
Pediatric		P	P	P	P	P	P	*P	P
Small Organ - Thyroid - - Breast - Testicle		P	P	P	P	P	P	*P	P
Neonatal Cephalic		P	P	P	P	P	P	*P	P
Adult Cephalic		P	P	P	P	P	P	*P	P
Cardiac		P	P	P	P	P	P	*P	P
Trans-esophageal		P	P	P	P	P	P	*P	P
Trans-Rectal									
Trans-Vaginal		P	P	P	P	P	P	*P	P
Trans-Urethral									
Intra-Luminal		N	N	N	N	N	N	*N	N
Peripheral Vascular		P	P	P	P	P	P	*P	P
Laparoscopic									
Musculo-Skeletal Conventional		P	P	P	P	P	P	*P	P
Musculo-Skeletal Superficial		P	P	P	P	P	P	*P	P
Other (Intra-Cardiac)		N	N	N	N	N	N	*N	N

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

* Combinations: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Device Use ✓

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K992631

Diagnostic Ultrasound Indications for Use Form
For
AcuNav™ Diagnostic Ultrasound Catheter

Intended Use: The AcuNav™ Diagnostic Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. The AcuNav™ is intended for use in right heart only.
Ultrasound System: Aspen™
Transducer: AcuNav™

Clinical Applications	A	B	M	PWD	CWD	Color Doppler	Power (Ampl.) Doppler	Combined (Specify)	Other (Specify)
Ophthalmic									
Fetal									
Abdominal									
Intra-operative - vascular									
Intra-operative Neurological									
Pediatric									
Small Organ - Thyroid - Breast - Testicle									
Neonatal Cephalic									
Adult Cephalic									
Cardiac		N	N	N	N	N	N	*N	N
Trans-esophageal									
Trans-Rectal									
Trans-Vaginal									
Trans-Urethral									
Intra-Luminal		N	N	N	N	N	N	*N	N
Peripheral Vascular									
Laparoscopic									
Musculo-Skeletal Conventional									
Musculo-Skeletal Superficial									
Other (Intra-Cardiac)		N	N	N	N	N	N	*N	N

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

* Combinations: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Prescription Device Use_____
(Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
For
Sequoia™ Diagnostic Ultrasound System

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

Clinical Applications	A	B	M	PWD	CWD	Color Doppler	Power (Ampl.) Doppler	Combined (Specify)	Other Harmonic Imaging
Ophthalmic									
Fetal		P	P	P	P	P	P	*P	P
Abdominal		P	P	P	P	P	P	*P	P
Intra-operative (vascular)		P	P	P	P	P	P	*P	P
Intra-operative Neurological									
Pediatric		P	P	P	P	P	P	*P	P
Small Organ - Thyroid- - Breast - Testicle		P	P	P	P	P	P	*P	P
Neonatal Cephalic		P	P	P	P	P	P	*P	P
Adult Cephalic		P	P	P	P	P	P	*P	P
Cardiac		P	P	P	P	P	P	*P	P
Trans-esophageal		P	P	P	P	P	P	*P	P
Trans-Rectal									
Trans-Vaginal		P	P	P	P	P	P	*P	P
Trans-Urethral									
Intra-Luminal		N	N	N	N	N	N	*N	N
Peripheral Vascular		P	P	P	P	P	P	*P	P
Laparoscopic									
Musculo-Skeletal Conventional		P	P	P	P	P	P	*P	P
Musculo-Skeletal Superficial		P	P	P	P	P	P	*P	P
Other (Intra-Cardiac)		N	N	N	N	N	N	*N	N

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

* Combinations: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Device Use ✓

(Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
For
AcuNav™ Diagnostic Ultrasound Catheter

Intended Use: The AcuNav™ Diagnostic Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. The AcuNav™ is intended for use in right heart only.
Ultrasound System: Sequoia™
Transducer: AcuNav™

Clinical Applications	A	B	M	PWD	CWD	Color Doppler	Power (Ampl.) Doppler	Combined (Specify)	Other (Specify)
Ophthalmic									
Fetal									
Abdominal									
Intra-operative - vascular									
Intra-operative Neurological									
Pediatric									
Small Organ - Thyroid - Breast - Testicle									
Neonatal Cephalic									
Adult Cephalic									
Cardiac		N	N	N	N	N	N	*N	N
Trans-esophageal									
Trans-Rectal									
Trans-Vaginal									
Trans-Urethral									
Intra-Luminal		N	N	N	N	N	N	*N	N
Peripheral Vascular									
Laparoscopic									
Musculo-Skeletal Conventional									
Musculo-Skeletal Superficial									
Other (Intra-Cardiac)		N	N	N	N	N	N	*N	N

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

* Combinations: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler

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Prescription Device Use_____
(Per 21 CFR 801.109)