JUL 9 2002

K021497

Section 8

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
ACUSON CORPORATION'S CYPRESS ULTRASOUND SYSTEM

Acuson Corporation has not disclosed its intent to market this device modification and requests this notification be held CONFIDENTIAL by FDA, and not be released to any Freedom of Information request or addressed with any outside parties.

Sponsor: Acuson Corporation
1220 Charleston Road
Mountain View, CA 94039-7303

Contact Person: Bob Leiker
Senior Regulatory Affairs Specialist
Telephone: (650) 694-5080
Fax: (650) 961-6158

Submission Date: May 8, 2002

Device Name: Acuson Cypress System

Common or Usual Name: Diagnostic ultrasound system

Classification:
Ultrasonic Pulsed Doppler Imaging System (90 IYN), class II (21 C.F.R. §892.1550)
Ultrasonic Pulsed Echo Imaging System (90 IYO), class II (21 C.F.R. §892.1560)
Diagnostic Ultrasound Transducer (90 ITX), class II (21 C.F.R. §892.1570)

Predicate Devices:
K010950, 6/27/2001, cleared as the Acuson Cypress Ultrasound System.

K982800, 9/22/98, cleared as the Ecton Lynx Ultrasound System, marketed as the Acuson Cypress Ultrasound System with subsequent modifications.

K991872, 6/16/99, cleared as Ecton Lynx Ultrasound System, marketed Acuson Cypress Ultrasound System with subsequent modifications.

Device Description:
The Acuson Cypress Ultrasound System is an ultrasound imaging platform which is designed for use with a variety of internal and external transducers. The Acuson Cypress System is a compact and portable diagnostic ultrasound system with a fold-up keyboard, an integrated LCD type display, and interchangeable electronic transducers. The user interface includes a keyboard, an intuitive layout of specialized controls, color GUI display and Doppler audio.

Intended Use:
The Acuson Cypress ultrasound system with the 7L3 transducer, the 2MHz CW transducer, and additional calculations is a modification to the previously cleared Cypress system that has already been cleared by FDA for Fetal, Abdominal, Intra-Operative (Cardiac), Pediatric, Neonatal Cephalic, Cardiac (Adult), Cardiac (Pediatric), Trans-esophageal, Peripheral Vascular, Other (Intra-Luminal), and Other (Intra-Cardiac) Indications. No new intended uses are claimed for the modifications.

Technological Characteristics and Substantial Equivalence:
The modified Cypress System is substantially equivalent to the predicate devices with respect to intended use and indications for use, principles of operation, and technological characteristics of design construction, and materials. It is comparable in key safety and effectiveness features.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 9 2002

Mr. Bob Leiker
Senior Regulatory Affairs Specialist
Acuson Corporation
1220 Charleston Road
MOUNTAIN VIEW CA 94039

Re: K021497
Trade Name: The Acuson Cypress System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasound pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulaton Name: Diagnostic ultrasound transducer
Regulatory Class: II
Product Code: 90 IYN, IYO and ITX
Dated: June 11, 2002
Received: June 12, 2002

Dear Mr. Leiker:

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 Acuson Cypress System, as described in your premarket notification:

Transducer Model Number

6 MHz Linear Array External Model 7L3
2 MHz Continuous Wave Doppler External, Model Auxiliary CW

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 (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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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 Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

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

Enclosure(s)

Diagnostic Ultrasound Indications for Use
For The Acuson Cypress System

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

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	(Other) Harmonic Imaging
Opthalmic										
Fetal		P	P	P	P	P	P			P
Abdominal		P	P	P	P	P	P			P
IntraOperative (Cardiac)		P	P	P	P	P	P			P
IntraOperative Neurological										
Pediatric		P	P	P	P	P	P			P
Small Organ (Specify)										
Neonatal Cephalic		P	P	P	P	P	P			P
Adult Cephalic										
Cardiac (Adult)		P	P	P	P	P	P			P
Cardiac (Pediatric)		P	P	P	P	P	P			P
Transesophageal		P	P	P	P	P	P			P
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular		P	P	P	P	P	P			P
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Other (Intra-Luminal)		P	P	P	P	P	P			P
Other (Intra-Cardiac)		P	P	P	P	P	P			

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

Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021497

Diagnostic Ultrasound Indications for Use For The Acuson Cypress System

6 MHz Linear Array External Transducer,
Model Name: 7L3

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

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	(Other) Harmonic Imaging
Opthalmic										
Fetal		N	N	N		N	N			N
Abdominal		N	N	N		N	N			N
IntraOperative (Cardiac)		N	N	N		N	N			N
IntraOperative Neurological										
Pediatric		N	N	N		N	N			N
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Adult)		N	N	N		N	N			N
Cardiac (Pediatric)		N	N	N		N	N			N
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular		N	N	N		N	N			N
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Other (Intra-Luminal)										
Other (Intra-Cardiac)										

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

Additional Comments: The transducer being added is new, but the indications are not new to the Cypress Ultrasound System.

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021497

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use
For The Acuson Cypress System

2 MHz Continuous Wave Doppler External Transducer,
Model Name: Auxiliary CW

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

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	(Other) Harmonic Imaging
Opthalmic										
Fetal					N					
Abdominal					N					
IntraOperative (Cardiac)										
IntraOperative Neurological										
Pediatric					N					
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Adult)					N					
Cardiac (Pediatric)					N					
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular					N					
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Other (Intra-Luminal)										
Other (Intra-Cardiac)										

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

Additional Comments: The transducer being added is new, but the indications are not new to the Cypress Ultrasound System.

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021497

Prescription Use (Per 21 CFR 801.109)