K013849
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DEC 0 3 2001

510(k) Summary for
TETRAD Model TC-EC7-ACP, -L5-, -L7-, -V4-ACP Transducers

1. SPONSOR

TETRAD Corporation
357 Inverness Drive, Suite A.
Englewood, CO 80112-5866

Contact Person: Charles F. Hottinger, Ph.D., RAC,
Regulatory Affairs Consultant

Telephone: 408-741-1006

Date Prepared: October 29, 2001

2. DEVICE NAME

Proprietary Name: TETRAD Model TC-EC7-ACP, -L5-, -L7-, -V4-ACP Transducers

Common/Usual Name: Ultrasound Transducers

Classification Name: Diagnostic Ultrasound Transducer
(21 CFR 892.1570, 90-ITX)

3. PREDICATE DEVICES

Acuson Aspen™ Ultrasound System, (including Transducers EC7, L5, L7, V4): K991805

4. INTENDED USE

The TETRAD Model TC-EC7-ACP, -L5-, -L7-, -V4-ACP Transducers are intended for diagnostic ultrasound imaging or fluid flow analysis of the human body; specific indications for use a tabulated in Section 4.3 of this submission.

5. DEVICE DESCRIPTION

Technical specifications for the Model TC-EC7-ACP, -L5-, -L7-, -V4-ACP Transducers are as follows:

Specifications	Tetrad TC-EC7-ACP	Tetrad TC-L5-ACP	Tetrad TC-L7-ACP	Tetrad TC-V4-ACP
Center Frequency	7.0 MHz nominal	6.0 MHz nominal	8.0 MHz nominal	4.0 MHz nominal
Number of Elements	128	128	128	128
Radius of Curvature	12.5	NA	NA	NA
Bandwidth —6dB	60% nominal	60% nominal	60% nominal	58% nominal
Elevation width	6 mm	4.1 mm	4.1 mm	15 mm
Elevation Focus	22 mm	20 mm	20 mm	90 mm
Lens material	Silicone	Silicone	Silicone	Silicone
Pitch	0.2 mm	0.3 mm	0.3 mm	0.5 mm

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The TETRAD Model TC-EC7-ACP, -L5-, -L7-, -V4-ACP Transducers are substantially equivalent to the corresponding Acuson products which are currently in commercial distribution in the United States, since the subject devices are functionally similar and have the same intended uses as the corresponding predicate transducers. The only substantive differences being the following points that were determined during the clearance of the TC-C3-ACP (an equivalent to the Acuson C3 Transducer) under K002193.

- The TETRAD Transducers are not intended for Fetal Doppler applications on the Acuson 128XP (a Track 1 device).
- The acoustic output levels of the TETRAD Transducers are equal to or slightly lower than those of their respective corresponding Acuson Transducers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 3 2001

TETRAD Corporation
% Mr. Mark Job
Program Manager
TUV Product Service, Inc.
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K013849
Trade Name: TETRAD Model TC-EC7-ACP, TC-L5-ACP, TC-L7-ACP,TC-V4 ACP Transducers
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasound Transducer
Regulatory Class: II
Product Code: 90 ITX
Dated: November 19, 2001
Received: November 20, 2001

Dear Mr. Job:

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 Aspen and 128XP Diagnostic Ultrasound Systems as described in your premarket notification:

Transducer Model Number
TC-L7-ACP
TC-L5-ACP
TC-EC7-ACP
TC-V4-ACP

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,

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 FORM

K013849

System: ____ACUSON Aspen and 128XP Systems_____
Transducer: TC-EC7-ACP
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[a]	Combined Modes[b]	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N[1]	N[1]	N[1,c]		N[1,c]	N[1,c]	
	Abdominal	N[1]	N[1]	N[1]		N[1]	N[1]	
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N[1]	N[1]	N[1]		N[1]	N[1]	
	Trans-vaginal	N[1]	N[1]	N[1]		N[1]	N[1]	
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color M, Power (Ampl.) Doppler.
[b] B+M; B+PWD; B+Color Doppler, B+PWD+Color Doppler
[c] Excludes Doppler or Doppler combination modes for Fetal application with 128XP
Additional Comments: N[1]: corresponding Acuson probe previously cleared under K991805.
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ____ACUSON Aspen and 128XP Systems_____
Transducer: TC-L5-ACP
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[a]	Combined Modes[b]	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N[1]	N[1]	N[1,c]		N[1,c]	N[1]	
	Abdominal	N[1]	N[1]	N[1]		N[1]	N[1]	
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N[1]	N[1]	N[1]		N[1]	N[1]	
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color M, Power (Ampl.) Doppler
[b] B+M; B+PWD; B+Color Doppler, B+PWD+Color Doppler.
[c] Excludes Doppler or Doppler combination modes for Fetal application with 128XP
Additional Comments: N[1]: corresponding Acuson probe previously cleared under K991805.
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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013849

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ____ACUSON Aspen and 128XP Systems_______
Transducer: TC-L7-ACP
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[a]	Combined Modes[b]	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N[1]	N[1]	N[1, c]		N[1, c]	N[1, c]	
	Abdominal	N[1]	N[1]	N[1]		N[1]	N[1]	
	Intra-operative (Specify)[d]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)	N[1]	N[1]	N[1]		N[1]	N[1]	
	Neonatal Cephalic	N[1]	N[1]	N[1]		N[1]	N[1]	
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	N[1]	N[1]	N[1]		N[1]	N[1]	
	Musculo-skel. (Superficial)	N[1]	N[1]	N[1]		N[1]	N[1]	
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	N[1]	N[1]	N[1]		N[1]	N[1]	
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N[1]	N[1]	N[1]		N[1]	N[1]	
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color M, Power (Ampl.) Doppler
[b]B+M; B+PWD; B+Color Doppler, B+PWD+Color Doppler.
[c]Excludes Doppler or Doppler combination modes for Fetal application with 128XP
[d]:Intra-operative: abdominal, cardiac.
Additional Comments: N[1]: corresponding Acuson probe previously cleared under K991805.
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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ____ACUSON Aspen and 128XP Systems_____
Transducer: TC-V4-ACP
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[a]	Combined Modes[b]	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N[1]	N[1]	N[1,c]		N[1,c]	N[1,c]	
	Abdominal	N[1]	N[1]	N[1]		N[1]	N[1]	
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

[a] Includes Color M, Power (Ampl.) Doppler
[b]B+M; B+PWD; B+Color Doppler, B+PWD+Color Doppler.
[c]Excludes Doppler or Doppler combination modes for Fetal application with 128XP

Additional Comments: N[1]: corresponding Acuson probe previously cleared under K991805.
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