

OCT 18 1999



K992580

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July 23, 1999

## **510(k) Summary Fetal Assessment CAP**

### **Name and Address**

Acuson Corporation  
1220 Charleston Road  
Mountain View, CA 94043

### **Contact Person**

William E. Welch  
Manager, Regulatory Affairs  
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### **Common, Classification & Proprietary Names**

Common Name:	Digital Ultrasound Image Analysis System
Classification Name:	Ultrasonic Pulsed Echo Imaging System
Proprietary Name:	Fetal assessment CAP or 3D Surface Rendering

### **Predicate Device**

TomTec Echo-View K934139

### **Device Description**

The Fetal Assessment CAP<sup>®</sup> 1.1 is a software module for high performance computer systems based on Microsoft Windows NT<sup>™</sup> 4.0 operating system standards. Fetal Assessment CAP<sup>®</sup> 1.1 is proprietary software for the analysis, storage, retrieval and reconstruction of ultrasound B-mode images.

The data can be acquired by a TomTec acquisition station or B-mode (2D) acquisition capable Ultrasound systems. With the Fetal Assessment CAP a 3 dimensional display can be reconstructed.



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**Intended Use**

Fetal Assessment CAP@ 1.1 is intended to retrieve, analyze and store digital ultrasound images for computerized 3-dimensional image processing.

Fetal Assessment CAP can import digital 2D or 3D image file formats for 3D display.

The software can be used with ultrasound systems previously cleared for B-mode imaging in obstetrics, gynecology, small organ, abdominal, endocavity, neurological, and intraoperative uses. I

**Technological Characteristics Comparison**

The Fetal assessment Cap is mainly a clinical application oriented set of the Echo-View system. The Acquisition methods are comparable to the EchoScan Acquisition methods. While the EchoView system provides diverse measurement functions, the Fetal Assessment CAP is a simple to use, qualitative 3D ultrasound tool, which provides 3D structures without any measurement functionality.

**Test Discussion**

Testing was performed according to internal company procedures. Software testing and validation were done at the module and system level according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release.

**Test Conclusions**

Test results support the conclusion that actual device performance satisfies the design intent. Actual device performance as tested internally conforms to the system performance specifications.

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William E. Welch



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850William E. Welch  
Manager, Regulatory Affairs  
Acuson Corporation  
1220 Charleston Road  
P.O. Box 7393  
Mountain View, CA 94039-7393Re: K992580  
3D Surface Rendering and Fetal Assessment CAP  
(Clinical Application Package)  
Dated: July 27, 1999  
Received: August 2, 1999  
Regulatory Class: II  
21 CFR 892.1560/Procode: 90 IYO

Dear Mr. Welch:

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 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 (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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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Diagnostic Ultrasound Indications for Use Form

Ultrasound System: See Comments Below

Transducer: See Comments Below

Clinical Applications	A	B	M	PWD	CWD	Color Doppler	Power (Ampl.) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P								
Abdominal		P								
Intra-operative (Specify)		P								
Intra-operative Neurological		P								
Pediatric		P								
Small Organ		P								
- Thyroid		P								
- Breast		P								
- Testicle		P								
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal		P								
Trans-Vaginal		P								
Trans-Urethral										
Intra-Luminal										
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: 3D\_Surface\_Rendering\_software can be used with any previously cleared ultrasound system and transducers capable of B-mode imaging and cleared for the above indications for use. \_\_\_\_\_

PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes

David A. Seymour  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K992580