K02 2896

Section 9 OCT 0 3 2002

510(k) Summary of Safety and Effectiveness

Acuson Corporation's Cypress CSV12 Software Viewer

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) 961-6168

Submission Date: August 30, 2002

Device Name: CSV12 Software Viewer, an accessory for the Acuson Cypress Ultrasound System

Common or Usual Name: Picture Archival and Communications System

Classification:
Picture Archival and Communications System (LLZ) class II (21CFR §892.2050)

Predicate Device:
K021497, July 09, 2002, cleared as the Acuson Cypress System

Device Description:
This modification is a software-only version of the Acuson Cypress Diagnostic Ultrasound System Image Viewer and is described as the CSV12 Software Viewer.

The modifications implemented in the CSV12 Viewer Software are to provide off-line image management of ultrasound studies and images on a PC and may be operated independently as a software-only product.

The CSV12 Software Viewer, when running on a personal computer (PC) duplicates the patient database, study storage, viewing, and quantification capability of the Cypress ultrasound system. This provides clinicians with a simple means of viewing studies off-line. Because it can read the full-resolution R-Theta file formats of the Cypress diagnostic ultrasound images, the CSV12 Software Viewer displays images in real-time without any compression, duplicating the original quality of the images on the Cypress diagnostic ultrasound system.

Intended Use:
The intended use of the CSV12 Software Viewer is acceptance, transfer, display, storage, and digital processing of Cypress diagnostic ultrasound images and image manipulation and quantification. No new intended uses are claimed for the modifications.

Technological Characteristics and Substantial Equivalence:
The modified CSV12 Software Viewer is substantially equivalent to the predicate device, Cypress Diagnostic Ultrasound System Image Viewer, with respect to intended use and indications for use, principles of operation, and technological characteristics and design. It is comparable in key safety and effectiveness features. Studies may be transmitted in DICOM or native Cypress format, to an integrated magneto-optical drive, or over a network.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 3 2002

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

Re: K022896
Trade/Device Name: CSV12 Software Viewer
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: August 30, 2002
Received: September 3, 2002

Dear Mr. Leiker:

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) that do not require approval of a premarket approval application (PMA). 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 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

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

Enclosure

K02 2896

Section 10

Indications For Use

The intended use of the CSV12 Software Viewer is for the acceptance, transfer, display, storage, and digital processing of Cypress Diagnostic Ultrasound System images, including image manipulation and quantification.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022896