K042620

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510(k) Summary
Sonata 3-D
Tetrad Corporation

DEC 23 2004

510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21 CFR 807.92(a).

807.92(a)(1)

Submitter Information

Dennis R. Dietz, Chief Technical Officer
Tetrad Corporation
357 Inverness Drive South Unit A
Englewood, Colorado 80112
Phone: 303-754-2326
Fax: 303-754-2329

Contact person: Dennis R. Dietz

Date: September 7, 2004

807.92(a)(2)

Trade Name: Sonata 3-D

Common Name: Digital Ultrasound Imaging System

Classifiction Name: System, Imaging, Pulsed Echo, Ultrasonic

Classification Number: 90IYO

807(a)(3)

Predicate Device

Sonora Medical Systems	Baby Face	K994385

Additional substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

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Comparison Chart for Substantial Equivalence

	Sonora Medical Systems Baby Face K1722606	Tetrad Corporation Sonata 3-D
Basic Function	Adds 3-D imaging capability to commercial 2-D ultrasound imaging systems.	Adds 3-D imaging capability to commercial 2-D ultrasound imaging system.
Hardware	Cyrix 266 MHz	Pentium IV 2.8 GHz
	Frame Grabber (VHS/S-VHS Input)	Frame Grabber digital via real time memory mapping in RAM
	Video Out	Video out via Sonata System
	Hand held controller	System keyboard control
Software features	Volume data acquisition w/frame grabbing of video data b/w while using a Gyroscopic sensor system.	Volume data acquisition w/frame grabbing of digital data b/w while scanning free-hand.
	Conditioning and transformation of the acquired data into a Cartesian volume	Conditioning and transformation of the acquired data into a Cartesian volume
	Surface rendering	Surface rendering
	Segmentation of structures from 3-D data.	Segmentation of structures from 3-D data.
	No quantitative evaluation.	No quantitative evaluation.
	No measurements or calculations.	No measurements or calculations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2004

Dennis R. Dietz, Ph.D.
Chief Technical Officer
Tetrad Corporation
357 Inverness Drive South, Unit A
ENGLEWOOD CO 80112

Re: K042620
Trade/Device Name: Sonata 3-D Visualization Tool
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: 90 IYO
Dated: November 18, 2004
Received: December 7, 2004

Dear Dr. Dietz:

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 (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 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 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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

Indications for Use

510(k) Number (if known): K042620

Device Name: Sonata 3-D Visualization Tool

Indications for Use: Intended to be used by or under the direction of a physician for 3-D clinical imaging in fetal applications. This is only to be used in conjunction with the 2300 Ultrasound Imaging system marketed under the model name 'Sonata' or 'Telocin', labeled as 2300 Ultrasound Imaging System manufactured by Tetrad Corporation.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042620