

MAR 16 2000

510(k) Summary
Baby Face
Sonora Medical Systems

510(k) Summary

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

807.92(a)(1)

Submitter Information

Colleen Hittle, Official Correspondent
7992 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916
Facsimile: (317) 577-9070

Contact Person: Colleen Hittle

Date: December 23, 1999

807.92(a)(2)

Trade Name: Baby Face
Common Name: Digital Ultrasound Image Analysis System
Classification Name(s): System, Imaging, Pulsed Echo, Ultrasonic
Classification Number: 90IYO

807.92(a)(3)

Predicate Device(s)

EchoTech 3D FreeScan K980308

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

510(k) Summary
Baby Face
Sonora Medical Systems

807.92(a)(5)

Intended Use(s)

Baby Face is intended to be used by qualified medical personnel (1) to visualize features in a reconstructed 3D image that they may wish to examine more closely in routine 2D fetal diagnostic ultrasound imaging examinations, and (2) to assist them in communicating diagnostic results in a form that may be more easily understood by referring physicians and patients. It does not provide quantitative measurements or diagnostic interpretations.

510(k) Summary
 Baby Face
 Sonora Medical Systems

Comparison Chart for Substantial Equivalence

	EchoTech 3D FreeScan K980308	Sonora Medical Systems Baby Face
Basic Function	Adds 3D imaging capability to commercial 2D ultrasound imaging systems	Adds 3D imaging capability to commercial 2D ultrasound imaging systems
Hardware	Pentium II 400 MHz	Cyrix 266 MHz
	Frame Grabber (VHS/S-VHS Input)	Frame Grabber (VHS/S-VHS Input)
	Video out	Video out
	Foot pedal	Handheld controller
Software features	Volume data acquisition w/frame grabbing of video data b/w while using an Electro magnetic sensor system	Volume data acquisition w/frame grabbing of video data b/w while using a Gyroscopic sensor system
	Conditioning & transformation of the acquired data into a Cartesian volume	Conditioning & transformation of the acquired data into a Cartesian volume
	Surface rendering	Surface rendering
	Segmentation of structures from 3D data	Segmentation of structures from 3D data
	Quantitative evaluation	No
	Measurements & calculations	No



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2000

Colleen Hittle
Official Correspondent
Sonora Medical Systems
1830 Boston Ave., Suite D
Longmont, CO 80501

Re: K994385
Baby Face (3-D Surface Rendering Accessory for
Diagnostic Ultrasound Systems)
Dated: December 23, 1999
Received: December 28, 1999
Regulatory class: II
21 CFR 892.1560/Procode: 90 IYO

Dear Ms. Hittle:

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) 594-4591. 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" (21CFR 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Indications for Use Statement

Applicant: Sonora Medical Systems

510(k) Number (if known): K994385

Device Name: Baby Face

Indications For Use:

Intended to be used by or under the direction of a physician and in conjunction with standard ultrasound for 3D clinical imaging in fetal applications

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over The Counter

(Per 21 CFR, 801.109)

(Optional Format 1-2-96)

David C. Bergman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K994385