

MAY 6 1998

K980308

January 23, 1998

510(k) Summary EchoTech 3D FreeScan

Submitter (Consultant) Name and Address

Morningstar Consulting Group, Inc.
P. O. Box 218
Indian Hills, CO 80454

Submitter (Consultant) Contact Person

Kevin Morningstar, Senior Consultant
phone (303) 697-8198
fax: call first

Manufacturer Name and Address

EchoTech 3D Imaging Systems GmbH
Zeppelinstr. 4
D-85399 Hallbergmoos
Germany

Manufacturer Contact Person

Peter Wlczek, Product Line Manager
Phone 49 811 5556 0
fax 49 811 5556 20

Common, Classification & Proprietary Names

Common Name:	Digital Ultrasound Image Analysis System
Classification Name:	Ultrasonic Pulsed Echo Imaging System
Proprietary Name:	EchoTech 3D FreeScan

Predicate Device

TomTec Echo-Scan K963807 dated December 18, 1996.

Device Description

The EchoTech 3D FreeScan is a high performance computer system based on Intel motherboard and Microsoft DOS/Windows standards. It incorporates a commercially available image digitizer circuit board and proprietary software for the acquisition, analysis, storage and retrieval of digital 3D ultrasound image data sets. The device is an add-on accessory for any existing diagnostic imaging ultrasound system.

The device records ultrasound transducer spatial position in six degrees of freedom during use. Coordinate tracking is achieved with a miniature magnetic field sensor within a transmitted pulsed magnetic field. This is done by attaching a plastic holding plate to the probe of the host ultrasound system, to which the receiver of an electromagnetic sensor device is attached.

2D ultrasound images are acquired sequentially in a series of steps as the ultrasound transducer is swept across the patient scan site. The resulting set of digitized 2D images is then converted into a 3D data volume.

Intended Use

The ECHOTECH 3D FreeScan system is indicated for acquisition of related sets of 2D ultrasound images and 3 dimensional reconstruction of diagnostic ultrasound images. It is intended to acquire, analyze, store and retrieve digital ultrasound images for computerized 3-dimensional image processing. It is an add-on accessory for existing ultrasound imaging systems, and is intended to record position and movement of ultrasound transducers for the systematic acquisition of 2 dimensional image slices throughout a volume of interest. It is intended as a general purpose digital 3D ultrasound image processing tool for cardiology, radiology, neurology, gastroenterology, urology, surgery, orthopedics, oncology, obstetrics and gynecology.

Technological Characteristics Comparison

The EchoTech 3D FreeScan is nearly identical in performance and intended use to the TomTec EchoScan, except that the EchoScan features an assortment of computer controlled probe carriage devices and incorporates respiration gating.

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. Additional system testing was done by a third party standards test house.

Test Conclusions

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



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850EchoTech 3D Imaging Systems GmbH
c/o Kevin Morningstar,
Senior Consultant
Morningstar Consulting Group, Inc.
P.O. Box 218
Indian Hills, CO 80454Re: K980308
EchoTech 3D FreeScan
Dated: April 4, 1998
Received: April 6, 1998
Regulatory class: II
21 CFR 892.1560/Procode: 90 IYO

Dear Mr. Morningstar:

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 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K980308

Device Name: ECHOTECH 3D FreeScan

Indications for Use:

The ECHOTECH 3D FreeScan system is indicated for acquisition of related sets of 2D ultrasound images and 3 dimensional reconstruction of diagnostic ultrasound images. It is intended to acquire, analyze, store and retrieve digital ultrasound images for computerized 3-dimensional image processing. It is an add-on accessory for existing ultrasound imaging systems, and is intended to record position and movement of ultrasound transducers for the systematic acquisition of 2 dimensional image slices throughout a volume of interest. It is intended as a general purpose digital 3D ultrasound image processing tool for radiology, neurology, gastroenterology, urology, surgery, orthopedics, oncology, obstetrics and gynecology.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerson
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K980308

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use