K023255

510(k)
Addition of VPan Module to
Technos^{Mp} Ultrasound Imaging System
Biosound Esaote

FEB 11 2003

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 Densmore, Official Correspondent
8000 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916
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Contact Person: Colleen Hittle Densmore

Date: January 15, 2003

807.92(a)(2)

Trade Name:	Technos MP Ultrasound Imaging System (Addition of VPan Module)	
Common Name:	Ultrasound Imaging System	
Classification Name(s):	Ultrasonic pulsed doppler imaging system	892.1550
Classification Number:	90IYN 90IYO	

807.92(a)(3)

Predicate Device(s)

Esaote	AU6 (Technos/TechnosMP)	K014168

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

807.92(a)(5)

Intended Use(s)

The VPan (View Panoramic) Module is being added to the Technos^{Mp} ultrasound imaging system to provide panoramic, wide field-of-view images for easier orientation of anatomy and pathology.

The Technos^{Mp} ultrasound imaging system is intended to be used by a physician for diagnostic imaging in cardiac, abdominal, peripheral vascular, fetal, pediatric, small organ, neonatal cephalic, transrectal, transvaginal, intraoperative abdominal, intraoperative peripheral vascular, laparoscopic, adult cephalic, other-urological and musculoskeletal applications.

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Comparison Chart for Substantial Equivalence

	Acuson Sequoia 512 FreeStyle Extended Imaging Software K022567	Esaote Technos/TechnosMp VPan Module This Submission
Scanning Method	Manual movement of probe across anatomy to be imaged	Manual movement of probe across anatomy to be imaged
Intended Use	Provides panoramic, wide field-of-view images for easier orientation of anatomy & pathology	Provides panoramic, wide field-of-view images for easier orientation of anatomy & pathology
Measurements	X, Y Linear distances	X, Y Linear distances
Image Manipulation	Pan / zoom / rotate	Pan / zoom / rotate
Transducer types	All general imaging transducers	Convex / Linear / Phased Array
Image Format	Spliced B-mode	Spliced B-mode

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2003

Ms. Colleen Densmore
Official Correspondent
Biosound Esaote, Inc.
8000 Castleway Drive
INDIANAPOLIS IN 46250

Re: K023255
Trade/Device Name: Technos MP Ultrasound Imaging System Addition of VPan Module
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: 90 IYN and IYO
Dated: January 15, 2003
Received: January 16, 2003

Dear Ms. Densmore:

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 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 the 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" (21CFR Part 807.97) you may obtain. 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

Indications for Use

510(k) Number (if known): K023255-R

Device Name: _____

Indications for Use:

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Prescription Use ✓

David A. Seguora

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023255

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

Concurrence of CDRH, Office of Device Evaluation (ODE)