JAN - 5 2005

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).

K043360

807.92(a)(1)

Submitter Information

Carri Graham, Official Correspondent
7992 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916, extension 103
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Contact Person: Carri Graham

Date: December 1, 2004

807.92(a)(2)

Trade Name: IMT.LAB software

Common Name: Picture archiving and communications system

Classification Name(s): System, Image Processing, Radiological

Classification Number: 90 LLZ

807.92(a)(3)

Predicate Device(s)

SonoMetric Health	SonoCalc	K030223
Phillips	QLAB	K021966

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

807.92(a)(6)

Technological Characteristics

ESAOTE believes that IMT.LAB is substantially equivalent to the SonoMetric Health's SonoCalc product (K030223) and to the Philips Medical Systems' QLAB product (K021966)

Characteristic	ESAOTE IMT.LAB Via this Submission	SonoMetric Health SonoCalc (K030223)	Philips Medical Systems QLAB (K021966)
Intended use	The IMT.LAB software is a Windows 2000/XP software package to be used on a personal computer for the automatic measurement of the intima media thickness of the carotid artery from video images obtained from Esaote Pie ultrasound systems.	The SonoCalc software is a Windows-based application program used on a personal computer for the automatic measurement of the intima media thickness of the carotid artery from images obtained from ultrasound systems	The Q LAB Quantification software is a Windows 2000/Windows XP software application package. It is designed to view and quantify image data acquired on Philips Medical Systems ultrasound products.
Image source	Ultrasound images	Ultrasound images	Ultrasound images
Operating environment, system and hardware	Stand alone application program for use on a personal computer with Microsoft Windows	Stand alone application program for use on a personal computer with Microsoft Windows	Stand alone application program for use on a personal computer with Microsoft Windows
Image format	DICOM, JPEG and Windows BMP	JPEG and Windows BMP	AVI and Windows BMP
Image storage and report generation	Yes	Yes	Yes
Automatic distance measurement of the intima media thickness of an artery	Yes	Yes	Yes
Classification	90LLZ 892.2050	90LLZ 892.2050	90LLZ 892.2050
Image Compression	JPEG Loss-less	JPEG Lossy	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 2005

Pie Medical
% Ms. Carri Graham
Consultant
The Anson Group
7992 Castleway Drive
INDIANAPOLIS IN 46250

Re: K043360
Trade/Device Name: IMT.LAB Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: December 1, 2004
Received: December 7, 2004

Dear Ms. Graham:

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): _____

Device Name: IMT.LAB Software

Indications for Use:

The IMT.LAB software is a Windows 2000/XP software application package to be used on a personal computer for the automatic measurement of the intima media thickness of the carotid artery from video images obtained from Esaote Pie ultrasound systems.

Prescription Use __X____ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043360