K061961

SEP - 6 2006

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

Carri Graham, Official Correspondent
11460 N. Meridian Street, Suite 150
Carmel, IN 46032
Phone: (317) 569-9500
Facsimile: (317) 569-9520

Contact Person: Carri Graham

Date: July 7, 2006

807.92(a)(2)

Trade Name: ART.LAB

Common Name: Picture Archiving and Communication System

Classification Name(s): Image Processing System 892.2050

Classification Number: 90IYO
90IYN
90ITX
90LLZ

807.92(a)(3)

Predicate Device(s)

K043360	IMT.LAB	Pie Medical
K961144	Cardiovision MS. 2000	Touritu Engineering Co., Inc.
K032875	SSD-5500	Aloka

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

807.92(a)(4) **Device Description**

The ART.LAB software product is an optional software package to be used on an external personal computer for the real time automatic measurement of the Intima Media Thickness, diameter and distension of the carotid artery. The measurements are based upon RF signal processing obtained from Esaote or Pie Medical ultrasound systems. The Arterial Stiffness Indicator is calculated from the distension and blood pressure (systolic and diastolic). The ART.LAB software operates in conjunction with an ultrasound system, a linear probe and is installed on an external PC, used for signal processing.

Specifications:
Ultrasound scanner with Fast-B-mode scanning capabilities and a linear probe
PC P3 1 GHz with 256 MG memory
Microsoft Windows 98 or XP
Data acquisition card (for acquisition of RF-signals obtained from ultrasound system)
Connection cable (from ultrasound system to PC, for RF, Z & trigger signals)
ART.LAB software

807.92(a)(5) **Intended Use(s)**

ART.LAB is a software package to be used on an external personal computer for the real time automatic measurement of the Intima Media Thickness, diameter and distension of the carotid artery from RF based signal processing obtained from Esaote or Pie Medical ultrasound systems. The Arterial Stiffness Indicator is calculated from distension and blood pressure (systolic and diastolic).

807.92(a)(6) Technological Characteristics

Characteristic	Esaote ART.LAB Via this submission	Esaote IMT.LAB K043360	Touritu Engineering Co., Inc. Cardiovision MS-2000 K961144	Aloka SSD-5500 K032875
Intended use 1. IMT	The ART.LAB software is a software package to be used on an external personal computer for the real time automatic measurement of the intima media thickness of the carotid artery based on RF signal processing obtained from Esaote or Pie Medical ultrasound systems.	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.		
2. Arterial Stiffness	The ART.LAB software is a software package to be used on an external personal computer for the real time automatic measurement of the diameter and distension of the carotid artery from RF based signal processing obtained from Esaote or Pie Medical ultrasound systems. The Arterial Stiffness Indicator is calculated from the distension and blood pressure (systolic and diastolic).		The MS-2000 is used by health care professionals to measure blood pressure data (systolic, diastolic and mean pressure) and heart pulse rate. The MS-2000 also generates pulse wave patterns which can be used as an initial screening device to determine if patients have potential underlying cardiovascular disease that might require more specific diagnostic evaluations by physicians or other health care providers. The MS-2000 calculates the Arterial Stiffness Index (ASI) based on the pulse wave patterns and the blood pressure .	The Aloka SSD-5500 contains the e-Technology which is a technique which measures the stiffness of blood vessels. The e-Technology is based on the simultaneous and continuous realtime assessment of changes in vessel diameter and blood flow velocity during the heart cycle. The diameter change is monitored by tracking of the two vessel walls and velocities are registered by Color Doppler. The combination of the ultrasound system with the e-Technology permits assessment of arterial stiffness parameters.
Image source	Ultrasound RF data	Ultrasound images	Blood pressure	Ultrasound RF data
Operating environment, system and hardware	Integrated application in ultrasound system	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	Integrated application in ultrasound system.
Image format	Proprietary RF data file format	DICOM, JPEG and Windows BMP TIFF	Microsoft ACESS files	Proprietary RF data file format
Image storage and report generation	Yes	Yes	Yes	Yes
Automatic distance measurement of the intima media thickness of an artery	Yes	Yes	No	Yes
Automatic measurement of the arterial stiffness of an artery	Yes	No	Yes	Yes
Classification	90IYN, 90ITX, 90IYO, 90LLZ	90LLZ 892.2050	DXN 870.1130	90IYN, 90ITX, 90IYO
Image Compression	No	JPEG – loss less	N/A	No

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Pie Medical
% Ms. Carri Graham
Consultant
Anson Group, LLC
11460 N Meridian St., Ste 150
CARMEL IN 46032

SEP - 6 2006

Re: K061961
Trade/Device Name: ART.LAB
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 7, 2006
Received: July 11, 2006

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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): K061961

Device Name: ART.LAB

Indications for Use:

ART.LAB is a software package to be used on an external personal computer for the real time automatic measurement of the Intima Media Thickness, diameter and distension of the carotid artery from RF based signal processing obtained from Esaote or Pie Medical ultrasound systems. The Arterial Stiffness Indicator is calculated from distension and blood pressure (systolic and diastolic).

Prescription Use ___X___ (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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061961