K040686

JUL 3 0 2004

510K Summary of Safety and Effectiveness

(Completed on July 2004)

This summary of safety and effectiveness is provide in accordance with 21 CFR 807.92

1. Submitter's Name

Intelligence in Medical Technologies
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Contact person :

Scott Pease
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Hartland WI 53029
Tel :414-704-6979
Fax : 414-327-1417

Summary's Date preparation: Submitted March 1, 2004 (completed July 7th 2004)

2. Device trade name: M'Ath® Std

Common name: Ultrasound Medical Image Measurement Software

Classification Name: 892.2050-System, Image processing, Radiological.

3. Predicate substantially equivalent devices:

- K021966, Q Lab Software, Advanced Technology Laboratories, Inc. (dba Philips Ultrasound); --
- K030223, Sonocalc, SonoMetric Health, LLC.

4. Device description : M'Ath®Std is a software running on a stand alone computer under Microsoft Windows operating system. Images are captured from any ultrasound device. Proprietary algorithms are used to measure Intima Media Thickness (IMT).Storage of patient measurements values can be performed during the examination. These measurements help to detect early atherosclerosis in the carotid vascular bed.

Predicate device specifications comparison

	PRINCIPAL DEVICE	**PREDICATE DEVICE 1**	**PREDICATE DEVICE 2**
	Intelligence in Medical Technologies (IMT)	**Advanced Technology Laboratories (ATL)**	**SonoMetric Health ,LLC**
	M'Ath Std	**Q Lab Software (K021966)**	**Sonocalc (K030223)**
Computer /Operating System	PC Based Hardware and Microsoft Windows operating system.	PC Based Hardware and Microsoft Windows operating system.	PC Based Hardware and Microsoft Windows operating system.
User Interface	PC Keyboard mouse (2 buttons)	PC Keyboard Mouse	PC Keyboard Mouse
Image Source	Ultrasound	Ultrasound	Ultrasound
Image Format	AVI, JPEG, GIF, TIFF, BMP, PCX, PCD, TGA, EPS, IMG.	AVI,BMP	JPEG and BMP
Data Storage (image and Video)	Yes	Yes	Yes
Report Generation	Yes	Yes	Yes
Measurement of Intima Media Thickness	Yes	Yes	Yes
Semi Automatic Detection (User points out where to detect)	Yes	Yes	Yes
Edge Detection	Yes	Yes	Yes
Quality Index	Yes	No	Unknown

5.Intended use
M'Ath® software is a Windows based application program running on a personal computer that is intended to aid the physician in the organisation of patient data relating to the ultrasound images or video acquired during vascular examination by sonography, and including patient characteristics. Additionally the software allows making measurements to determine the intima media thickness of the carotid artery from the accurate image and store them with the patient file.

Performance data: There are no section 514 performance standards for this class of device for assisting in the determination of its substantial equivalence.

Conclusions drawn from clinical and non clinical test data:
Not required for determination of substantial equivalence for th is class of device, though publication of some clinical data are contained in this premarket submission.

Substantial equivalence summary: The Intelligence in Medical Technologies (IMT), M'Ath Software is comparable and substantially equivalent to a legally marketed predicate device. The intended use of the Intelligence in Medical Technologies (IMT) software is the same as that of the of the predicate devices "Q Lab Software" marketed by Advanced Technologies Laboratories (d.b.a Philips Ultrasound) and "Sonocalc" marketed by Sonometrics Health ,LLC". No new safety or effectiveness issues are raised with M'Ath™ Std.The subject device has substantially equivalent technological characteristics, features, specifications, materials, mode of operation, and intended use as a legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 0 2004

Intelligence in Medical Technologies
% Mr. Scott J. Pease, ASQ CQA-HACCP
Consultant, Regulatory/QS
PEASE Consulting
P.O. Box 222
HARTLAND WI 53029

Re: K040686
Trade/Device Name: M'Ath® Std
Regulatory Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: July 12, 2004
Received: July 19, 2004

Dear Mr. Pease:

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 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 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

Applicant: Intelligence in Medical Technologies

510(k) Number (if known): K040686

Device Name: M'Ath Std Software

Indications For Use: M'Ath Std software is a Windows-based application program running on a personal computer that is intended to aid the physician in the organization of patient data relating to the ultrasound images or video acquired during echo-cardiology exams of the cardiovascular system, including the patient's characteristics. Additionally, the software allows the physician to makes measurements to determine the intima-media thickness of the carotoid artery from the acquired images and stores them with the patient file.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040686

Prescription Use ✓