510(k) Summary of Safety and Effectiveness

K030223

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

Date of preparation: 12/31/02

1. **Submitter**
   SonoMetric Health, LLC
   1373 E. Skyline Dr.
   Bountiful, UT 84010

FEB 0 6 2003

2. **Contact**
   Helmuth Fritz, MD, RVT
   SonoMetric Health, LLC
   1373 E. Skyline Dr.
   Bountiful, UT 84010
   Phone: (909) 553-2650
   Fax: (909) 790-5284
   hsfritz@hotmail.com

3. **Device Identification**
   Tradename: SonoCalc
   Common name: Medical image measurement software
   Classification: 892.2050 – Radiology – System, Image Processing

4. **Indications for use**
   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.

5. **Device Description**
   SonoCalc is a software package that runs on a stand-alone computer running a Microsoft Windows™ operating system. There is no dedicated medical equipment required for operation of this software application except for an ultrasound machine that is the source of images of the carotid artery. These images are digitally transferred from the ultrasound machine to the computer containing the software application. SonoCalc then uses proprietary techniques and algorithms to measure the Intima-Media Thickness (IMT) of either or both of the near or far wall(s) of the carotid artery. SonoCalc can generate a report indicating what the patient's IMT value is. This information is used adjunctively with other medical data by a physician to help assess the cardiovascular health of a patient.

   SonoCalc also is capable of storing patient measurement values on the hard disk along with the images for future reference.

6. Substantial Equivalence

SonoMetric Health believes that SonoCalc is substantially equivalent to other legally marketed products, specifically the Q LAB software package (K021966) developed by ATL Ultrasound (d/b/a Philips Ultrasound) a Philips Medical System Company, when Q LAB is used for the automatic measurement of the IMT of the carotid artery.

Characteristic	SonoMetric Health SonoCalc	QLAB (K021966)
Intended use	Automatic measurement of intima media thickness of carotid arteries.	Automatic measurement of intima media thickness of carotid and other arteries.
Image source	Ultrasound images	Ultrasound images
Operating environment, system and hardware	Stand-alone application program for use on a personal computer operating with Microsoft Windows	Stand-alone application program for use on a personal computer operating with Microsoft Windows
Image format	JPEG and Windows BMP	AVI and BMP
Image storage and report generation	Yes	Yes

7. Performance standards

There are no Section 514 performance standards for this class of device. The SonoCalc software has been designed to comply with the following voluntary standards:

- ISO Joint Photographic Experts Group (JPEG) Image
- Microsoft Windows Bitmap (BMP) Image Encoding
- A ultrasound phantom and image calibration markings verification study for the SonoCalc software was performed. This test consisted of SonoCalc measuring the distance of targets in an ultrasound phantom from images obtained from a commercially available ultrasound system. The results of this test showed that the SonoCalc software performed equivalently to the commercial ultrasound system's caliper measurements of the same phantom
- A clinical validation comparison was performed using the SonoCalc software and manual measurements of subjects' IMT values. The study consisted of 120 ultrasound images obtained from 20 different subjects who were scanned with a commercially available ultrasound system. Manual caliper measurements of IMT values from the ultrasound system performed by 3 trained sonographers were compared to measurements of the same images performed by SonoCalc. The results of this study showed that the SonoCalc software performed equal to or better than the manual measurements with respect to accuracy and reproducibility

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 4 2003

SonoMetric Health, LLC
% Mr. N. E. Devine, Jr.
Responsible Third Party
Entela, Inc.
Madison Ave. SE
GRAND RAPIDS MI 49548

Re: K030223
Trade/Device Name: SonoCalc
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving 3033
and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: January 10, 2003
Received: January 22, 2003

Dear Mr. Devine:

This letter corrects our substantially equivalent letter of February 6, 2003 regarding the date.

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 on 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 describe 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" (21 CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained form the Division of Small Manufactures, 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,

for 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 Statement

510(k) Number (if known): K030223

Device Name: SonoCalc

Indication for Use:

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.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-counter Use _____
(Per 21 CFR 801.109)

David G. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030223

06