K122022

510(k) Summary

SEP 26 2012

Submitter's Name:	AtheroPoint™ LLC
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Contact Name:	Jasjit S. Suri
Date Summary Prepared:	June 21, 2012
Trade or Proprietary:	AtheroEdge™
Common or Usual Name:	Medical Image Processing Workstation
Classification Name:	System, Image Processing, Radiological, LLZ Picture Archiving and Communications, 21CFR 892.2050

Predicate Devices:

Device Name	510(k) Number
SonoCalc	K030223
IMT.LAB	K043360

5.0 Device Description, Indications of Use and Technology

5.0.1 Device Description and Its Technology

AtheroEdge™ is a software package that runs on a stand-alone computer running a Microsoft Windows™ XP or Microsoft Windows™ 7.0 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. AtheroEdge™ software provides a means of opening and displaying images in DICOM, ISO Joint Photographic Experts Group (JPEG) Image Compression Standard and Microsoft Windows's BMP formats. AtheroEdge™ then uses proprietary techniques and algorithms to automatically

measure the Intima-Media Thickness (IMT) and its variability of the distal (far) wall of the carotid artery in ultrasound image. AtheroEdge™ software provides a means for creating a region of interest on the distal (far) wall image and display by the software. AtheroEdge™ software provides a means of analyzing the content of the image data contained within the region of interest (ROI) and compute the IMT and its variability. AtheroEdge™ can generate, view and print a report indicating what the patient's IMT and its variability values. This information is used adjunctively with other medical data by a physician to help assess the cardiovascular health of a patient. AtheroEdge™ is also capable of storing patient measurement values in the database management system along with the images for future reference.

5.0.2 Device – Indications of Use

The AtheroEdge™ software is a Window's-based application program used on a personal computer for an automatic measurement of the Intima-Media Thickness (IMT) of the carotid artery from images obtained from ultrasound systems.

5.1 Device Comparison Table

AtheroEdge™ is substantially equivalent to other legally marketed products, specifically, the SonoCalc product (K030223) developed by SonoMetric Health, LLC and Esaote's IMT.LAB product (K043360), when SonoCalc and Esaote IMT.Lab is used for automated measurement of the IMT of the carotid artery. The technological characteristics comparison table is shown below:

Company Name	AtheroPoint™	Sono Metric Health	ESAOTE IMT.LAB
Product Name	AtheroEdge™	SonoCalc	IMT.LAB
510(k) no	Via this submission	K030223	K043360

Intended Use	The AtheroEdge™ software is a Windows-based application program used on a personal computer for the automatic measurement of the Intima-Media thickness (IMT) of the carotid Artery from images obtained from 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 (IMT) of the carotid Artery from images obtained from ultrasound systems.	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 (IMT) of the carotid artery from video images obtained from Esaote Pie ultrasound systems.
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's BMP	JPEG and Windows BMP	DICOM, JPEG and Windows BMP
Image storage and report generation	Yes	Yes	Yes
Automatic distance measurement of the Intima-Media thickness of carotid artery	Yes	Yes	Yes
Classification	90 LLZ 892.2050	90 LLZ 892.2050	90 LLZ 892.2050
Image Compression	JPEG Loss-less	JPEG Loss-less	JPEG Loss-less

5.2 Performance Testing and benchmarking

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

- Digital Imaging and Communications in Medicine (DICOM).
- ISO Joint Photographic Experts Group (JPEG) Image.
- Microsoft Windows Bitmap (BMP) Image Encoding.
- Two types of clinical validation and performance testing were performed:

(i) Benchmarking against the manual caliper measurements of IMT values taken from commercially available ultrasound system.

(ii) Benchmarking against expert reader's measurement of IMT values taken from two radiological expert ultrasound tracers and taking its average.

The validation study consisted of 200 carotid ultrasound images corresponding to 50 subjects, retrospectively taken from a longitudinal study and laboratory tested off-line. The carotid ultrasound images were scanned with a commercially available ultrasound system using a 13-5 MHz linear transducer of Sonoline Antares ultrasound scanner (Siemens, USA). The acquisition followed echo cardiology standards. The benchmarking results for both validation methods showed that AtheroEdge™ software performed within 5% tolerance of the (i) mean manual caliper measurements of IMT values taken from commercially available ultrasound system and (ii) mean expert reader's measurement of IMT values taken from two radiological expert ultrasound tracers.

5.3 Conclusion

The results of comparing the intended use, function, technological characteristics, mode of operation and specifications of the AtheroEdge™ with those predicate devices demonstrate that the AtheroEdge™ is substantially equivalent to existing products in the market today.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 26 2012

Jasjit S. Suri, PhD
Chief Executive Officer (CEO)
AtheroPoint™ LLC
208 Otter Gen Court
ROSEVILLE CA 95661

Re: K122022
Trade/Device Name: AtheroEdge
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 21, 2012
Received: July 10, 2012

Dear Dr. Suri:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use (IFU)

510(k) Number (if known): Pending

Device Name: AtheroEdge™

The AtheroEdge™ software is a Window's-based application program used on a personal computer for an automatic measurement of the Intima-Media Thickness (IMT) of the carotid artery from images obtained from ultrasound systems.

Prescription Use ___X___ OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
OIVD

510k K122882