K070244

FEB 9 2007

510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of the Premarket Notification for Aegis, in accordance with SMDA 1990.

Date Prepared: January 19th/2007

Identification of Submitter:

Submitted By: Sentinelle Medical Inc.
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Identification of Product:

Device Trade Name: Aegis
Device Common Name: Picture Archiving Communications System (PACS)
Regulation Number: CFR 892.2050
Device Classification: Class II
Classification Name: Image Processing System

Marketed Device:

Predicate Device: CADStream™ Version 4.0
Predicate Device Manufacturer: Confirma, Inc.
Predicate Device 510(k) Number: K043216
Date Received: 11/19/2004
Decision Date: 11/22/2004
Decision: Substantially Equivalent
Panel Code Device Reviewed by: Radiology
Panel Code Device Classified by: Radiology
Product Code: LLZ
Regulation Number: 892.2050
Device Classification: Class II

Device Description

Aegis is one of the components of a PACS (Picture Archiving and Communications System). Aegis is visualization software designed for breast imaging and intervention procedures. Aegis receives DICOM 3.0 images over a medical imaging network where its primary goal is to identify where and how deep a biopsy needle should be inserted into an imaged breast in order to strike a targeted lesion or region of interest, as chosen by a trained medical professional.

Indications for Use

Aegis is a software application that is intended for use in analyzing magnetic resonance imaging (MRI) medical images as well as other multi-modality images. Its primary goal is to identify where and how deep a biopsy or localization needle should be inserted into an imaged breast in order to strike a targeted lesion or region of interest, as chosen by a trained medical professional. Aegis receives images and data from various sources (including but not limited to CT, MR, US, computed and direct radiographic devices, secondary capture devices, scanners, imaging gateways or imaging sources). Aegis can be used to communicate, process, and display medical images. Users have access to various image processing and measurement tools to assist them in viewing images. These user-defined post-processing functions include image subtractions, multiplanar reformats, maximum intensity projections, and segmenting of regions based on enhancement characteristics.

The digitized mammographic images and/or ultrasound images displayed by Aegis on the laptop display (or on any display not approved by the FDA for such purposes) must not be used for primary diagnostic interpretation.

Typical users of Aegis are trained medical professionals, including but not limited, to radiologists, technologists and clinicians. When interpreted by a skilled user, this device provides information that may be useful in screening and diagnosis. Patient management decisions should not be made solely on the results of Aegis analysis.

Technological Characteristics

Aegis is a stand-alone software package that is pre-installed onto laptops before being sold to customers. It can also be installed on any computer as long as it meets the minimum requirements stated in the User Manual.

The system allows digital image processing and measurement capability and can transmit images from remote devices to itself over a medical imaging network.

Aegis does not contact the patient, nor does it control any life-sustaining devices. A physician providing ample opportunity for competent human intervention interprets images and information being displayed.

Comparison with Predicate Devices

Aegis is substantially equivalent to the following image processing system used by radiologists:

Confirma CADStream Version 4.0
Manufacturer: Confirma Inc.
510(k) Number: K043216

This workstation allows easy selection, review, processing, and media interchange of multi-modality images from a variety of diagnostic imaging systems.

Conclusion

Aegis provides additional features to further integrate radiological and interventional workflow. The potential hazards have been studied and controlled as part of the product development process, including risk analysis, test and design considerations, and planned verification and validation testing processes. Aegis provides images and functionality comparable to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

FEB 9 2007

Sentinelle Medical, Inc.
c/o Mr. Daniel W. Lehtonen
Intertek Testing Services
2307 East Aurora Road
Unit B7
TWINSBURG OH 44087

Re: K070244
Trade/Device Name: Aegis
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 23, 2007
Received: January 25, 2007

Dear Mr. Lehtonen:

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

Indication(s) For Use

510(k) Number: K070244

Device Name: Aegis

Indications for Use:

Aegis is a software application intended for use in analyzing magnetic resonance imaging (MRI) medical images as well as other modality images.

Aegis includes software to support the use of interventional breast coils and MR fiducial localization devices to perform MR-guided breast interventional procedures (BRIGHT™). Its primary goal is to identify where and how deep a biopsy or localization needle should be inserted into an imaged breast in order to strike a targeted lesion or region of interest, as chosen by a trained medical professional.

Aegis receives images and data from various sources (including CT, MR, US, computed and direct radiographic devices, secondary capture devices, scanners, imaging gateways and imaging sources). Aegis can be used to communicate, process, and display medical images. Users have access to various image processing and measurement tools to assist them in viewing images. These user-defined post-processing functions include image subtractions, multiplanar reformats, maximum intensity projections, and segmenting of regions based on enhancement characteristics.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a FDA approved monitor that offers at least 5 MPixel resolution and meets other technical specifications reviewed and accepted by the FDA.

Typical users of Aegis are trained medical professionals, including radiologists, technologists and clinicians. When interpreted by a skilled user, this device provides information that may be useful in screening and diagnosis. Patient management decisions should not be made solely on the results of Aegis analysis.

Prescription Use (Part 21 CFR 801 Subpart D):	X	AND/OR	Over-The-Counter Use (Part 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)

David G Segerman

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K070244