K060779

APR 5 2006

GE Healthcare

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

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Date Prepared: March 15, 2006.

PRODUCT IDENTIFICATION

Name: Advanced Vessel Analysis II

Classification Name: Accessory to Computed Tomography System per 21 CFR 892-1750

Manufacturer : General Electric Medical Systems
283, rue de la Minière
78533 Buc Cedex, FRANCE

Distributor: GE Healthcare, P.O. Box 414, Milwaukee, WI 53210

Marketed Devices The Advanced Vessel Analysis II is substantially equivalent to the devices listed below:

- Model: Smart Vessel Analysis Option, 510(k) # K993792
- Model: CardIQ Analysis III, 510(k) # K041267
- Model: Auto Bone, 510(k) # K031871

- Manufacturer: General Electric Medical Systems, Buc, France

Device Description:

CT Advanced vessel analysis (AVA II / AVA 2) is a post processing analysis software package designed to assist Radiologists, Cardiologists, and other clinicians in the evaluation and assessment of vascular anatomy.

- Advanced vessel analysis is a software post-processing package for the Advantage Workstation (AW) platform, CT scanners and PACS reading stations. It is an additional tool for the analysis of 3D CT angiographic images/data providing a number

of display, measurements and batch filming/archive features to study user-selected vessels which include but are not limited to stenosis analysis, thrombus, pre/post stent planning procedures and directional vessel tortuosity visualization.

Indications for Use:

Advanced Vessel Analysis II is intended to provide an optimized non-invasive application to analyze vascular anatomy and pathology and aid in determining treatment paths from a set of Computed Tomography (CT) Angiographic images.

Advanced Vessel Analysis II (AVA II) is a post processing application option for the Advantage Workstation (AW) platform, CT Scanner or PACS stations, which can be used in the analysis of 2D and 3D CT Angiography images/data derived from DICOM 3.0 compliant CT scans for the purpose of cardiovascular and vascular disease assessment. This software is designed to support the physician in assessment of stenosis analysis, pre/post stent planning and directional vessel tortuosity visualization.

AVA II automatic visualization tools provide the users with the capabilities to facilitate segmentation of bony structures for accurate identification of the vessels. Once vessels are visualized, tools are available for sizing the vessel, analyzing calcified and non-calcified plaque to determine the densities of plaque within a coronary artery, measure area's of abnormalities within a vessel.

Comparison with Predicate:

AVA II is substantially equivalent to the predicate devices listed above :

Device Name	FDA Clearance Number
Smart Vessel Analysis	K993792
CardIQ Analysis III	K041267
Auto Bone	K031871

Adverse Effects on Health:

The potential hazards are identified in a risk management summary (hazard analysis) and are controlled by:

- Software Development, Validation and Verification Process to ensure performance to specifications, Federal Regulations and user requirements.
- Adherence to industry and international standards.

Conclusions:

Advanced Vessel Analysis II does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the Advanced Vessel Analysis II to be equivalent to those of CardIQ Analysis III (K041267), Auto Bone (K031871), Smart Vessel Analysis (K993792).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 5 2006

GE Healthcare
% Mr. Neil E. Devine, Jr.
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K060779
Trade/Device Name: Advanced Vessel Analysis II
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 20, 2006
Received: March 22, 2006

Dear Mr. Devine:

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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 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): K060779

Device Name: Advanced Vessel Analysis II

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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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060779