K061625

JUN 26 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: April 13, 2006

PRODUCT IDENTIFICATION

Name: AutoBone 2
Classification Name: Accessory to Computed Tomography System per 21 CFR 892-1750
Product code: JAK

Manufacturer: GE Medical Systems SCS
283, rue de la Minière
78533 Buc Cedex, FRANCE

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

Marketed Devices The AutoBone 2 is substantially equivalent to the devices listed below:

- Model: AutoBone , 510(k) # K031871
- Manufacturer: GE Medical Systems SCS, Buc, France

Device Description:

- AutoBone 2 is an optional software extension of the Volume Viewer application for Advantage Workstation. This software can be used in order to facilitate visualization of vessel features and assist in segmentation of bony and calcified structures

Indications for Use:

The AutoBone 2 option is a software package that is intended to facilitate segmentation of bony structures and calcifications from abdominal and extremity CT Angiography data.

Comparison with Predicate:

AutoBone 2 is substantially equivalent to the predicate devices listed below:

Device Name	FDA Clearance Number
AutoBone	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:

AutoBone 2 does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the AutoBone 2 to be equivalent to AutoBone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 26 2006

GE Healthcare
% Mr. Daniel W. Lehtonen
Responsible Third Party
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K061625
Trade/Device Name: AutoBone 2
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: June 9, 2006
Received: June 12, 2006

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

GE Healthcare

Indications for Use

510(k) number if known: K061625

Device name: AutoBone 2

Indications For Use:

The AutoBone 2 option is a software package that is intended to facilitate segmentation of bony structures and calcifications from abdominal and extremity CT Angiography data.

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

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061625