SEP 2 5 2001

510(k) Summary

K012106

1. Company Identification

AccuImage Diagnostics Corporation
400 Grandview Drive
South San Francisco, CA 94080
Phone (650) 875-0192
Fax (650) 875-0194
Contact Person: Oscar Gils Carbó
Email oscar@accuimage.com
Establishment Registration No. 2953774

2. Official Correspondent

Gary J. Allsebrook
Regulatory Management Services
16303 Panoramic Way
San Leandro CA 94578-1116
Phone (510) 276-2648
Fax (510) 276-3559
Email: regman1@home.com

3. Date of Submission

July 3, 2001

4. Device Name

Proprietary Name:	**AccuImage SmartGate Upgrade**: AccuImage EKG Gating Tool Enhancement for AccuScore 1.0.
Classification Name:	90JAK – CT, Image Processing
Device/Usual Name:	Gated Calcification Scoring of CT images.

5. Substantial Equivalence

The AccuImage Smartgate Upgrade Option is Substantially Equivalent to GE Medical Systems HiSpeed Lxi with SmartScore and the Vital Images Vscore with Gating options.

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6. Device Description and Intended Use

Device Description

The *AccuImage Smartgate Upgrade* for AccuScore 1.0 is an additional software option to K990241, AccuView Diagnostic Imaging Workstation with AccuScore, AccuAnalyze, AccuShade, AccuVRT and AccuMIP plug-ins. The AccuShade plug-in is not currently marketed, and the AccuMIP plug-in is currently marketed with the name AccuProjector. The new *AccuImage Smartgate Upgrade* Gating Tool enhancement for AccuScore provides the capability of generating calcium scoring for gated images, thus minimizing adverse effects of heart movement.

Intended Use

Heart calcium scoring for gated CT images to minimize effects of heart movements.

7. Software Development:

The software was designed, developed, verified and validated according to written procedures. These procedures specify individuals within the organization responsible for developing and approving product specifications, software coding and testing, validation testing and field maintenance.

Performance Testing:

All software testing specified in the Software Product Development Plan will be successfully completed prior to market release.

8. Hazard Analysis

Hazard analysis on this product has been performed throughout the definition, design, coding and testing phases of product development and implementation. This process has emphasized:

- identification of potential hazards, their causes, and their effects;
- development of methodologies to control the occurrence of hazards and to constrain their effects; and
- Determine any effect on patient safety and system effectiveness.

The potential hazards associated with this software product are no different than those of other PACS components . These are primarily related to failure of computer system components, and may be variously obviated by

decisions taken by the customers of this product. None of these failures are expected to materially contribute to patient death or injury.

It is our conclusion that there is no hardware or software component, operating in a properly configured environment, whose failure or latent design defect would be expected to result in death or injury of a patient. Thus the "Level of Concern" is "Minor".

9. Safety Concerns

The hardware is "off-the-shelf" and complies with applicable electrical safety standards for standard PC hardware and peripherals.

10. Substantial Equivalence Comparison Chart

The following product(s) provides functions, which are substantially equivalent to this product:

Manufacturer	**GE Medical Systems**	**Vital Images**	**AccuImage**
Product Name	HiSpeed LX/i with SmartScore	Vscore with AutoGate option	AccuImage Smartgate Upgrade
510(k) Number	K980169	K003230	
Computer Platform	Not Known	PC / Windows workstation	Pentium / Windows workstation
Gating Option for Calcium Scoring	HiSpeed LX/i with SmartScore option	Match cardiac CT images with the corresponding EKG signal. This allows the physician to select images acquired when the heart was still.	Match cardiac CT images with the corresponding EKG signal. This allows the physician to select images acquired when the heart was still.
Type of CT scanners for which it is applicable	LightSpeed and HiSpeed GE CT scanners	EBCT and standard CT	EBCT and standard CT
Types of Gating	Prospective and Retrospective Gating	Images with either associated EKG signal or image-derived cardiac motion signal	Images with either associated EKG signal or image-derived cardiac motion signal

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 5 2001

AccuImage Diagnostics Corporation
% Mr. Gary Allsebrook
Official Correspondent
Regulatory Management Services
16303 Panoramic Way
SAN LEANDRO CA 94578-1116

Re: K012106
Trade/Device Name: AccuImage SmartGate Upgrade
Gated Calcification Scoring for CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-ray System
Regulatory Class: II
Product Code: 90 JAK
Dated: July 3, 2001
Received: July 6, 2001

Dear Mr. Allsebrook:

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 (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 described in your 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:

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). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

510(k) Number (if known): K012106

Device Name:

AccuImage SmartGate Upgrade: AccuImage EKG Gating Tool Enhancement for Accuscore 1.0

Indications For Use:

Heart calcium scoring for gated CT images to minimize effects of heart movements.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use____
(Per 21 CFR 901.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012106