K023100

OCT 1 1 2002

Section 2 Summary and Certification

510(k) Summary of Safety and Effectiveness

Date: September 17, 2002

Submitter: GE Medical Systems *Information Technologies*
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person: Lisa Lee Michels
Regulatory Affairs Specialist
GE Medical Systems *Information Technologies*
Phone: (262) 293-1609
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Device: Trade Name: AccuSketch Cardiac Quantitative Analysis System w/ Advanced Analysis Components

Common/Usual Name: Cardiac Image Analysis Station

Classification Names: System, Image Processing Radiological

Predicate Devices: CardioTrace K912829; *MUSE Cardiovascular Information System with Accusketch K992937

*NOTE: AccuSketch Cardiac Quantitative Analysis System w/ Advanced Analysis Components is being compared to AccuSketch, classification code LLZ, integrated into MUSE in K#992637. MUSE classification codes of DQK Programmable Diagnostic Computer (Class II) and DSI Detector & Alarm, Arrhythmia (Class III) are not applicable to AccuSketch component of MUSE.

Device Description: The AccuSketch Cardiac Quantitative Analysis System w/ Advanced Analysis Components is a PC based software system comprised of 4 individual programs used to view, capture/print, analyze and annotate images from cardiac catheterization procedures. AccuSketch is offered as a complete turn-key system or can be ported into other GE cardiac image devices for image analysis. The AccuSketch is a Personal Computer (PC) based software system designed to be permanently installed in a hospital in or near the cardiac catheterization laboratory. AccuSketch is comprised of four individual programs responsible for a specific function. Their purpose is to view, capture/print, analyze and annotate images from cardiac catheterization procedures.

Intended Use: The AccuSketch LV HL is intended to aid the Cardiologist or trained technician in providing and documenting an objective quantification of a patient's Left Ventricular function. The AccuSketch STN HL is intended to aid the Cardiologist or trained technician in providing and documenting an objective quantification of coronary artery stenosis (the amount of vessel closure due to coronary artery disease). The Image Capture system provides image capture and printing.

The CardioTree is an editable coronary tree tool used to electronically annotate and document the anatomy of the patient's vessels.

Technology: The AccuSketch Cardiac Quantitative Analysis System w/ Advanced Analysis Components employs the same functional scientific technology as its predicate devices.

Test Summary: The AccuSketch Cardiac Quantitative Analysis System w/ Advanced Analysis Components complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the AccuSketch Cardiac Quantitative Analysis System w/ Advanced Analysis Components:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing
- Safety testing
- Environmental testing

Conclusion: The results of these measurements demonstrated that the AccuSketch Cardiac Quantitative Analysis System w/ Advanced Analysis Components is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2002

Ms. Lisa Lee Michels
Regulatory Affairs Specialist
GE Medical Systems
Information Technologies
8200 West Tower Avenue
MILWAUKEE WI 53223

Re: K023100
Trade/Device Name: AccuSketch Cardiac Quantitative Analysis System [w]/Advanced Analysis Components
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: September 17, 2002
Received: September 18, 2002

Dear Ms. Michels:

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): K023100 ~~Unknown; 510(k) filed on September 17, 2002~~

Device Name: AccuSketch Cardiac Quantitative Analysis System w/Advanced Analysis Components.

Indications for Use:

AccuSketch Cardiac Quantitative Analysis System w/ Advanced Analysis Components is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. AccuSketch is intended to provide and document an objective quantification of coronary artery stenosis and measurement and quantification of left ventricular function. Also provided is the ability to digitize and store video images and the ability to interactively annotate and report current and post procedural patient cardiac status.

(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 801.109)

(Optional Format 1-2-96)

David A. Lepore

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023100