NOV 2 6 2002

GE Medical Systems
P.O. Box 414, W-709
Milwaukee, WI 53201

K023178

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).

Identification of Submitter: Larry A. Kroger, Ph.D.
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GE Medical Systems
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Summary prepared: 17 September 2002

Identification of Product: Digital Fluoroscopic Imaging System
Classification Name: Stationary X-ray System
Manufacturer: GE Medical Systems Europe
283, rue de la Minière
78530 Buc Cedex, France

Distributed by: GE Medical Systems, Milwaukee, WI

Marketed Devices: The Digital Fluoroscopic Imaging System is substantially equivalent to the currently marketed cardiographic system **LCV+ Version 2** so-called **Innova 2000** introduced in 2000 (K993037) that complies with the same or equivalent standards. The collimator used (Siemens model # 0468264 G052G) was introduced in the Siemens angiographic device **Sireskop** (version SX ou SD cleared under K971452) in 1997. The Review station used so-called **Advantage Workstation 4.1** was introduced in 2000 (K020483).

Device Description: The **Digital Fluoroscopic Imaging System** is designed to perform fluoroscopic x-ray examinations. The detector is comprised of amorphous silicon with a cesium iodide scintillator. The resulting digital image can be sent through a Fiber Channel link to an acquisition equipment then to network (in using DICOM) for applications such as post-processing, printing, viewing and archiving. **Digital Fluoroscopic Imaging System** consists of an angiographic monoplane positioner, a vascular table, an X-RAY system and a digital detector.

Materials: All construction and materials are compliant with UL 187 for the existing parts of the product and with UL 2601 for the new parts.

Design: There are hardware and software redundancies to prevent from single point failures that could cause unintended motion.

Energy Source: 480 VAC 50/60Hz.

Indications for Use: The **Digital Fluoroscopic Imaging System** is indicated for use in generating fluoroscopic images of human anatomy for diagnostic and intervention angiography procedures. It is intended to replace fluoroscopic images obtained through the image intensifier technology. This device is not intended for mammography applications.

Comparison with Predicate: The **41 cm Digital Fluoroscopic Imaging System** is substantially equivalent to the 20 cm Fluoroscopic system so-called Innova 2000 (Originally Cleared as the LCV+ Version 2; K993037).

Summary of Studies:

- **A clinical comparison study:** 6 radiologists from 3 hospitals: Saint-Luke's Hosp. (Bethlehem, Pennsylvania - US), Saint-Francis Hospital, (Peoria, Illinois – US); Centre Paris Nord (Sarcelles – France) compared digital images recorded on Innova 2000 and Innova 4100 from 11 pairs of patient sequences and found that the digital images from the Innova 4100 had equivalent image diagnostic capability.
- **A non-comparative clinical evaluation** of the Large Field of View (40 cm) image diagnostic capability has been conducted by the same group of radiologists as well.
- **A non-comparative clinical evaluation of fluoroscopy** in all FOV conducted in real time of the clinical procedures by three radiologists of Saint-Luke's.

Conclusions: GE considers the **41 cm Digital Fluoroscopic Imaging System** to be equivalent with the predicate device. The **41 cm Digital Fluoroscopic Imaging System** provides fluoroscopic images that result in equivalent diagnostic capabilities than the 20 cm images. The potential hazards, e.g., wrong measurements and misdiagnosis, are controlled by a risk management plan including:

- A hazard identification
- A risk evaluation
- A Software Development and Validation Process

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUL 30 2002

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems, Inc.
P.O. Box 414, W-709
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Re: K023178
Trade/Device Name: Innova 4100
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: September 20, 2002
Received: September 23, 2002

Dear Dr. Kroger:

This letter corrects our substantially equivalent letter of November 26, 2002.

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K023178

Device Name: **Digital Fluoroscopic Imaging System – Innova 4100**

Indications for Use

The **Digital Fluoroscopic Imaging System** is indicated for use in diagnostic and interventional angiographic procedures of human anatomy. It is intended to replace image intensifier fluoroscopic systems in all diagnostic or interventionnal procedures. This device is not intended for mammography applications.

(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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023178