AUG 25 2005

K052157

GE Healthcare
P.O. Box 414, W-400
Milwaukee, WI 53201 USA

Executive Summary

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.
Senior Regulatory Programs Manager
GE Healthcare
Tel. (262) 544-3894
Summary prepared: July 22, 2005

Identification of Product: Digital Fluoroscopic Imaging System
Device Trade Name: Innova CT option for Digital Fluoroscopic Imaging Systems Innova 4100, Innova 4100^{IQ}, Innova 3100, Innova 3100^{IQ}, Innova 2100^{IQ}
Classification Name: Fluoroscopic X-ray System
Manufacturer: GE Medical Systems SCS.
283, rue de la Minière
78530 Buc Cedex, France
Distributed by: GE Medical Systems, LLC, Milwaukee, WI

Marketed Devices: The GE Healthcare Innova CT option is substantially equivalent to the currently marketed DynaCT option of Siemens Vascular Angiographic system (K042646). The Innova CT is intended for use with Innova 4100 (renamed Innova 4100^{IQ} and previously cleared under K033244), Innova 3100 (renamed Innova 3100^{IQ} and previously cleared under K031637), and Innova 2100^{IQ} (or 2100-IQ previously cleared under K050489). This opinion is based on the information included in this premarket notification.

Device Description: The Innova CT imaging is offered as an option for Innova 4100 Innova 3100, Innova 2100^{IQ} (2100-IQ), 4100^{IQ} and Innova 3100^{IQ}.
The Digital Fluoroscopic Imaging Systems are designed to perform fluoroscopic x-ray examinations. The detector is comprised of amorphous silicon with a cesium iodine scintillator. The resulting digital image can be sent through a Fiber Channel link to an acquisition system then to network (in using DICOM)

for applications such as post-processing, printing, viewing and archiving. Digital Fluoroscopic Imaging System consists of a monoplane positioner, a vascular or cardiac table, an X-RAY system and a digital detector.

Materials: All construction and materials are compliant with UL 187 and IEC 60601-1 for the existing parts of the product and with UL 2601 and IEC 60601-1 for the new parts.

Design: The design is validated through Failures Modes Effects Analysis (FMEA) process, which allows managing the risks.

Energy Source: 480 VAC 50/60Hz.

Indications for Use: For Innova 4100, Innova 4100^{IQ}, Innova 3100, Innova 3100^{IQ}, Innova 2100^{IQ} with Innova 3T option:

The Innova systems are indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic and interventional procedures, and optionally, rotational imaging procedures. They are also indicated for generating fluoroscopic images of human anatomy for cardiology, diagnostic, and interventional procedures.
They are intended to replace fluoroscopic images obtained through image intensifier technology. Those devices are not intended for mammography applications.

Innova CT is a software option, which reconstructs 3D volumes from Rotational Fluoroscopy acquisition to provide images that assist the physician in diagnosis, surgical planning, interventional procedures and treatment follow-up.
Innova CT is intended for imaging bone and soft tissues as well as other internal body structures.
Innova CT is not intended for mammography applications

Comparison with The GE Healthcare option *Innova CT* is substantially equivalent to the currently marketed option DynaCT of Siemens Vascular Angiographic system cleared under K042646 .

- *Dyna CT indications for use:* DynaCT is an x-ray imaging software option, which allows the reconstruction of two-dimensional images acquired with a standard angiographic C-arm device into a three-dimensional image format.

DynaCT is intended for imaging both hard and soft tissues as well as other internal body structures for diagnosis, surgical planning, interventional procedures and treatment follow-up.

This opinion is based on the information contained in the comparison table and the product data sheets.

Summary of the Studies: Sample clinical data for the Innova CT option are included in this submission.

Conclusions: GE Healthcare considers that the Innova CT option for Digital Fluoroscopic Imaging Systems Innova 4100, Innova 4100^{IQ}, Innova 3100, Innova 3100 ^{IQ} and Innova 2100 ^{IQ} to be equivalent with the DynaCT option The potential hazards, related to the use of Innova CT option 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
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 2005

Mr. Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Healthcare
P.O. Box 414, W-400
MILWAUKEE WI 53201

Re: K052157
Trade/Device Name: Innova CT option for Digital Fluoroscopic Imaging Systems, Innova 4100, Innova 4100[IQ], Innova 3100, Innova 3100 [IQ], Innova 2100 [IQ]
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: IZI, JAA, and LLZ
Dated: August 5, 2005
Received: August 8, 2005

Dear Mr. Kroger:

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

C. Indications for Use

510(k) Number (if known): K052157

Device Name: Innova CT option for Digital Fluoroscopic Imaging Systems Innova 4100, Innova 4100^{IQ}, Innova 3100, Innova 3100^{IQ}, Innova 2100^{IQ}

Indications for Use:

- The Innova systems are indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic and interventional procedures, and optionally, rotational imaging procedures. They are also indicated for generating fluoroscopic images of human anatomy for cardiology, diagnostic, and interventional procedures. They are intended to replace fluoroscopic images obtained through image intensifier technology. This device is not intended for mammography applications.
- Innova CT is a software option which reconstructs 3D volumes from Rotational Fluoroscopy acquisition to provide images that assist the physician in diagnosis, surgical planning, interventional procedures and treatment follow-up.
- Innova CT is intended for imaging bone and soft tissues as well as other internal body structures.
- Innova CT is not intended for mammography applications

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 K052157