K061163

JUN - 7 2006

GE Healthcare

P.O. Box 414, W-440

Milwaukee, WI 53201 USA

1. 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: April 25, 2006

Identification of Product: Digital Fluoroscopic Imaging System
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 2121 ^{IQ}, Innova 3131 ^{IQ}, Innova 4100, Innova 4100^{IQ}, Innova 3100, Innova 3100^{IQ}, Innova 2100^{IQ} devices with ***Innova IVUS option*** are substantially equivalent to the currently marketed GE Healthcare Innova 2121 ^{IQ}, Innova 3131 ^{IQ}, Innova 4100, Innova 4100^{IQ}, Innova 3100, Innova 3100^{IQ}, Innova 2100^{IQ} devices (K060259, K033244, K052412, K031637, K050489)

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

Device Description: The ***Innova IVUS*** is offered as an option for Innova 2121^{IQ}, Innova 3131^{IQ} (cleared under K060259), Innova 4100 (cleared under K033244), Innova 3100 (cleared under K031637), Innova 2100^{IQ} (cleared under K050489), Innova 4100^{IQ} and Innova 3100^{IQ} (cleared under K052412).

The Innova 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 an a monoplane or biplane positioner, a vascular or cardiac table, an X-RAY system and one or two digital detectors.

The Innova IVUS option provides enhanced connectivity with third party intravascular ultrasound devices.

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 2121 ^{IQ}, Innova 3131 ^{IQ}, Innova 4100, Innova 4100^{IQ}, Innova 3100, Innova 3100^{IQ}, Innova 2100^{IQ} devices with ***Innova IVUS 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 IVUS option:

The Innova IVUS software option simplifies the clinical workflow associated with the use of Volcano IVUS products by:
(1) automatically synchronizing the patient demographic information (patient name, date of birth, DICOM attributes etc.) from Innova system with an IVUS imaging system,
(2) providing a remote access to commonly used IVUS functions from the Innova table side user interface.
(3) displaying the IVUS images on the multi-monitor display of the Innova cathlab system.

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Comparison with

The GE Healthcare Innova 2121 IQ, Innova 3131 IQ, Innova 4100, Innova 4100IQ, Innova 3100, Innova 3100IQ, Innova 2100IQ devices with Innova IVUS option are substantially equivalent to the currently marketed GE Healthcare Innova 2121 IQ, Innova 3131 IQ, Innova 4100, Innova 4100IQ, Innova 3100, Innova 3100IQ, Innova 2100IQ devices (K060259, K033244, K052412, K031637, K050489)

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

Summary of the Studies:

Innova 3131IQ, Innova 2121IQ, Innova 4100, Innova 4100IQ, Innova 3100, Innova 3100IQ and Innova 2100IQ with Innova IVUS option are considered substantially equivalent to the predicates in terms of image quality and diagnostic capabilities. Therefore, previously submitted clinical data are applicable for this submission.

Conclusions:

GE Healthcare considers that Innova IVUS option for Digital Fluoroscopic Imaging Systems Innova 3131IQ, Innova 2121IQ, Innova 4100, Innova 4100IQ, Innova 3100, Innova 3100IQ and Innova 2100IQ to be equivalent with the predicate devices. The potential hazards, related to the introduction of ***Innova IVUS*** options are controlled by a risk management plan including:

- A hazard identification (Attachment 8)
- A risk evaluation (Attachment 8)
- A Software Development and Validation Process (Attachment 7)

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

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Senior Regulatory Programs Manager
GE Medical Systems, LLC
P.O. Box 414, W-400
MILWAUKEE WI 53201

JUL 30 2012

Re: K061163
Trade/Device Name: Digital Fluoroscopic Imaging Systems-Innova 4100, Innova 4100^{IQ}, Innova 3100, Innova 3100^{IQ}, Innova 2100^{IQ}, Innova 3131^{IQ}, Innova 2121^{IQ} with Innova IVUS Option
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA and IYO
Dated: April 25, 2006
Received: April 26, 2006

Dear Dr. Kroger:

This letter corrects our substantially equivalent letter of June 7, 2006.

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

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2. Indications for Use

510(k) Number (if known): K061163

Device Name: **Digital Fluoroscopic Imaging Systems – Innova 4100, Innova 4100^{IQ}, Innova 3100, Innova 3100^{IQ}, Innova 2100^{IQ}, Innova 3131^{IQ}, Innova 2121^{IQ} with Innova IVUS option.**

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.
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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 IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legerman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061163