MAR 1 1 2005

GE Healthcare

P.O. Box 414, W-400

Milwaukee, WI 53201 USA

K050489

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: 07 February 2005

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 Innova 2100-IQ is substantially equivalent to the currently marketed Vascular Angiographic system Innova 3100 (K031637) and complies with the same or equivalent standards.
Optional feature InnovaSpin and the cardiac imaging modes in the Innova 2100-IQ are substantially equivalent to the Innova 2000/Innova 2000S systems cleared under K022322 and LCV+ Version 2 systems cleared under K993037.

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 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 positioner, a vascular or cardiac 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 IEC 60601-1 for the new parts.

Design:	There are hardware and software redundancies to prevent single point failures that could cause unintended motion.
Energy Source:	480 VAC 50/60Hz.
Indications for Use:	The Innova 2100-IQ system is indicated for use in generating fluoroscopic images of human anatomy for vascular angiography diagnostic and interventional procedures, and optionally, rotational angiography procedures. It is also indicated for generating fluoroscopic images of human anatomy for cardiology diagnostic and interventional procedures. It is intended to replace fluoroscopic images obtained through image intensifier technology. This device is not intended for mammography applications.
Comparison with Predicate:	The Innova 2100-IQ is substantially equivalent to the currently marketed Vascular Angiographic system Innova 3100 (K031637) and complies with the same or equivalent standards. The optional feature InnovaSpin and cardiac imaging modes in the Innova 2100-IQ are substantially equivalent to the Innova 2000/Innova 2000S systems cleared under K022322 and LCV+ Version 2 systems cleared under K993037. Innova 2100-IQ combines features from Innova 2000/LCV+ Version 2 and Innova 3100 to enable cardiac and vascular procedures. The indications of use for the predicative devices are given below: - The Innova 3100 System is indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, and optionally, rotational angiography procedures. It is intended to replace fluoroscopic images obtained through image intensifier technology. - Innova 2000 / Innova 2000S: The Digital Fluoroscopic Imaging Systems are indicated for use in generating fluoroscopic images of human anatomy for diagnostic and interventional cardiac angiography, and optionally, rotational cardiac angiography procedures. It is intended to replace fluoroscopic images obtained through the image intensifier technology. - The LCV+ Version 2 is indicated for use in generating fluoroscopic images of human anatomy for cardiology diagnostic / interventional procedures. It is intended to replace fluoroscopic images obtained through the image intensifier technology.

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Summary of the Studies: References in term of clinical data have been submitted for first digital products in the family introduced by GE Medical Systems-Europe ie LCV+ Version 2 for cardiology diagnostic and interventional procedures, and in Innova 4100 for vascular angiography diagnostic and interventional procedures. As Innova 2100-IQ is considered substantially equivalent to Innova 3100 (predicated by Innova 4100), and LCV+ Version 2 in terms of image quality and diagnostic capabilities, it is not applicable.

Conclusions: GE considers the 20 cm Digital Fluoroscopic Imaging System to be equivalent with the predicate devices. The potential hazards, e.g., wrong measurements and misdiagnosis, 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

JUL 30 2012

GE Medical Systems, LLC
% Mr. Daniel W. Lehtonen
Third Party Official
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K050489
Trade/Device Name: Digital Fluoroscopic Imaging System-Innova 2100-IQ
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: February 23, 2005
Received: February 25, 2005

Dear Mr. Lehtonen:

This letter corrects our substantially equivalent letter of March 11, 2005.

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.

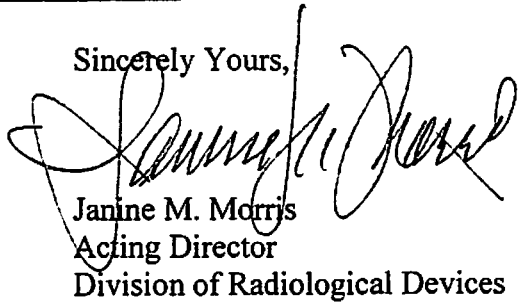
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

Indications for Use

510(k) Number (if known): K050489

Device Name: Digital Fluoroscopic Imaging System – Innova 2100-IQ

Indications for Use:

The Innova 2100-IQ system is indicated for use in generating fluoroscopic images of human anatomy for vascular angiography diagnostic and interventional procedures, and optionally, rotational angiography procedures. It is also indicated for generating fluoroscopic images of human anatomy for cardiology diagnostic and interventional procedures. It is intended to replace fluoroscopic images obtained through image intensifier technology. This device is not intended for mammography applications.

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 Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050489