K060259

FEB 2 2 2006

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: 20 January 2006

Identification of Product: Innova 3131-IQ and Innova 2121-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 Innova 3131^{IQ} (3131-IQ) and 2121^{IQ} (2121-IQ) are substantially equivalent respectively to the currently marketed Vascular Angiographic systems Innova 3100^{IQ} (K052412) and Innova 2100^{IQ} (K050489) and comply with the same or equivalent standards.

Biplane feature is substantially equivalent respectively to the Advantx LCN+ and Advantx LC/LP+ (both cleared under K974367).

Tilt table Elegance option is substantially equivalent to the Digital Fluoroscopic Imaging System, Model Innova K033244.

Device Description: The Digital Fluoroscopic Imaging Systems are designed to perform biplane fluoroscopic x-ray examinations. The detectors are comprised of amorphous silicon with a cesium iodine scintillator. The resulting digital images can be sent through a Fiber Channel link to an acquisition system then to network

(using DICOM) for applications such as post-processing, printing, viewing and archiving. The Digital Fluoroscopic Imaging System consists of a biplane positioner, a vascular table, an X-ray system, two X-ray generators/sources and two digital detectors.

Materials: All construction and materials are compliant with UL 60601 and with IEC 60601-1.

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 **3131^{IQ}** (3131-IQ) and **2121^{IQ}** (2121-IQ) biplane systems are indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic and interventional procedures, and optionally, rotational angiography 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. These devices are not intended for mammography applications.

Comparison with Predicates: The Innova 3131^{IQ} (3131-IQ) and 2121^{IQ} (2121-IQ) are substantially equivalent respectively to the currently marketed Vascular Angiographic systems Innova 3100^{IQ} (K052412) and Innova 2100^{IQ} (K050489) and comply with the same or equivalent standards.

Biplane feature is substantially equivalent respectively to the Advantx LCN+ and Advantx LC/LP+ (both cleared under K974367).

Tilt table Elegance option is substantially equivalent to the Digital Fluoroscopic Imaging System, Model Innova (K033244).

Innova 3131^{IQ} combines features from Innova 3100^{IQ} with the biplane positioning system of Advantx LCN+ to enable single plane and biplane cardiac and vascular procedures.
Innova 2121^{IQ} combines features from Innova 2100^{IQ} with the biplane positioning system of Advantx LCN+ and Adx to enable single plane and biplane cardiac and vascular procedures.

The indications of use for the predicative devices are given below:

- The Innova 3100[IQ] system is indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic and interventional procedures, and optionally, rotational imaging 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. It is not intended for mammography applications.

- Innova 3D is a software option which reconstructs 3D volumes from Rotational Fluoroscopy acquisition to assist the physician in diagnosis, surgical planning, interventional procedures and treatment follow-up. It is not intended for mammography applications.

- InnovaSpin is a software option that permits fast spin rotational angiography. It is not intended for mammography applications.

- 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.

-The Advantx LCN+ is indicated for use in generating fluoroscopic images of human anatomy for vascular angiography and interventional single plane and biplane procedures.

- The Advantx LC/LP+ is indicated for use in generating fluoroscopic images of human anatomy for cardiology diagnostic/interventional single plane and biplane procedures.

Figure 1 summarizes the equivalence of Innova 3131[IQ] and 2121[IQ] (2121-IQ) systems with the various predicates.

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-SCS, i.e., **LCV+ Version 2** for cardiology diagnostic and interventional procedures, and **Innova 4100** for vascular angiography diagnostic and interventional procedures. As Innova 3131[IQ] and 2121[IQ] are considered substantially equivalent to Innova 3100[IQ] and 2100[IQ], predicated by Innova 4100 and LCV+ Version 2 in terms of image quality and diagnostic capabilities, reference to clinical data is not necessary (see attachment F for detailed justifications)

Conclusions: GE considers the 30cm and 20 cm Digital Biplane Fluoroscopic Imaging Systems 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 D)
- A risk evaluation (Attachment D)
- A Software Development and Validation Process (Attachment F)

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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WAUKESHA WI 53188

JUL 30 2012

Re: K060259
Trade/Device Name: Digital Fluoroscopic Imaging Systems-Innova 3131^{IQ} & Innova 2121^{IQ}
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: January 31, 2006
Received: February 1, 2006

Dear Dr. Kroger:

This letter corrects our substantially equivalent letter of February 22, 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.

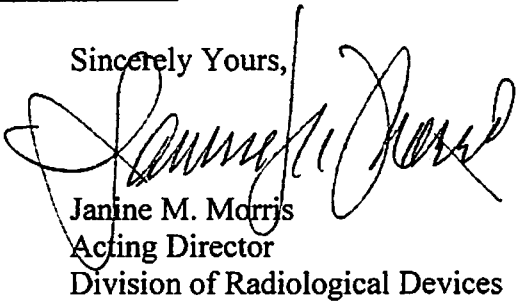
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

STATEMENT OF INTENDED USE

510(k) Number (if known): K060259

Device Name: **Digital Fluoroscopic Imaging Systems – Innova 3131^{IQ} & Innova 2121^{IQ}**

Indications for Use

The **Innova 3131^{IQ}** (3131-IQ) and **2121^{IQ}** (2121-IQ) biplane systems are indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic and interventional procedures, and optionally, rotational angiography 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. These devices are 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 K060259