



'AUG 26 2004

K042053
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GE Healthcare
P.O. Box 414, W-400
Milwaukee, WI 53201 USA

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: 5 July 2004

Identification of Product: Digital Fluoroscopic Imaging System
Classification Name: Fluoroscopic X-ray system – 21 CFR 892.1650
Manufacturer: GE Medical Systems Europe
283, rue de la Miniere
78530 Buc Cedex, France
Distributed by: GE Healthcare, Milwaukee, WI

Marketed Devices: The GE Healthcare Innova 4100 and Innova 3100, with the new Bolus Chasing option for angiography of lower limbs are substantially equivalent to GE Advantx LCV+ (K960575). This opinion is based on the information contained in the comparison table, and the product data sheets.

Device Description: The new Bolus Chasing is offered as an option for Innova 4100 and 3100, already cleared under K033244 and K031637.

Materials: All construction and materials are compliant with UL 2601 and IEC 60601-1.

Design: Controls of operation of XRAY, injection and table motion are intended to prevent from useless exposures to XRAY/contrast agent during a Bolus Chasing sequence in case of failure from one of these parameters (i.e., XRAY, injection and table motion).

Energy Source: 380 - 480 VAC; 50/60Hz.

Indications for Use: The Digital Fluoroscopic Imaging System with ***Bolus Chasing*** option is indicated for use in generating fluoroscopic images of human anatomy for diagnostic and intervention; the option Bolus enables to perform subtraction angiography of lower

limbs. This device is not intended for mammography applications.

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Comparison with

The GE Healthcare new Bolus Chasing option for Innova 4100, 3100 systems, is substantially equivalent to the GE Health Care *Advantx LCV+ Bolus Chasing* which is part of the *Advantx LCV+ system (K960575)*.

Conclusions:

GE Healthcare considers that the ***Bolus Chasing*** option for their 41 cm and 31 cm Digital Fluoroscopic Imaging Systems Innova 4100 and Innova 3100 to be equivalent with the predicate device. The potential hazards, related to the introduction of new ***Bolus Chasing*** option, are controlled by a risk management plan including:

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



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

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

Re: K042053
Trade/Device Name: Innova 4100, Innova 3100 with optional Bolus Chasing
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: July 29, 2004
Received: July 30, 2004

Dear Dr. Kroger:

This letter corrects our substantially equivalent letter of August 26, 2004.

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.

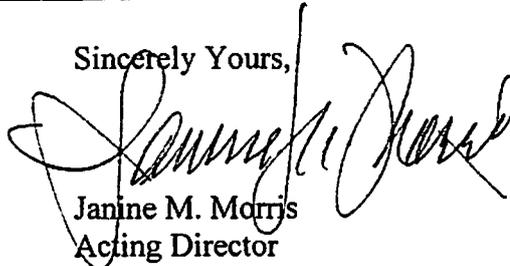
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

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): K042053

Device Name: **Digital Fluoroscopic Imaging Systems – Innova 4100, Innova 3100 with optional Bolus Chasing.**

Indications for Use

The two **Digital Fluoroscopic Imaging Systems** are 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 interventional procedures. These devices are not intended for mammography applications. The **Bolus Chasing** option submitted here is intended to perform subtracted angiography in real time of the lower limbs for diagnostic purpose.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801-109)

OR Over-The-Counter Use _____

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042053