JAN 1 6 2003

GE Medical Systems

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

K024200

This 510(k) summary of Safety and Effectiveness informartion is submitted in accordance with the requirements of 21 CFR 807.87(h).

Submitter: GE Medical Systems
PO Box 414
Milwaukee. WI 53201

Contact Person: Larry A. Kroger
Senior Regulatory Programs Manager
Tel: 262-544-3894; Fax: 262-548-4768

Date: 18 December 2002

Device Name: Innova 2000 and Innova 2000S (Mobile version)

Manufacturer: GE Medical Systems Europe
283 rue de la Minière
78530 Buc Cedex. France

Distributed by: GE Medical Systems
PO Box 414
Milwaukee. WI 53201

Marketed Device: Innova 2000 and Innova 2000S cleared under K022322.

Device Description: The Innova 2000 and 2000S (Mobile version) - hereafter referred to as Mobile Innova 2000 and Innova 2000S - are composed of the the same components as the predicate device.
The principle system components include a C-arm, image acquisition, processing and archiving capabilities.

Materials: Materials and construction are equivalent to

the predicate device and are compliant with UL 2601-1, IEC 60601-1 and associated collateral standards and applicable sections of 21 CFR Subchapter J.

Indications for use: The Digital Fluoroscopic Imaging systems are indicated for use in generating fluoroscopic images of the human anatomy for diagnostic and interventional cardiac angiography procedures. These systems can be operated in a mobile or fixed site environment.

Comparison with Predicate Device: The Mobile Innova 2000 and Innova 2000S systems are a modification of, and of comparable type and substantially equivalent to the currently marketed Innova 2000 and Innova 2000S systems cleared under K022322. They have the same technological characteristics, have comparable key safety and effectiveness features, use the same basic design, construction and materials and have the same intended use as the predicate devices.

Summary of Studies: The devices have been evaluated for electrical, mechanical and radiation safety and conform to applicable medical device safety and performance standards.

Conclusions: GE Medical Systems considers that the Mobile Innova 2000 and Innova 2000S systems are substantially equivalent to the currently cleared Innova 2000 and Innova 2000S systems. Their intended use and fundamental scientific technology are the same as the predicate devices. The design and development process of the manufacturer conforms with 21 CFR 820 and ISO 9001/EN 46001 quality systems. The devices also conform to applicable medical device safety and performance standards.

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

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

JUL 30 2012

Re: K024200
Trade/Device Name: Innova 2000 and 2000S (Mobile Version)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA and OXO
Dated: December 18, 2002
Received: December 20, 2002

Dear Dr. Kroger:

This letter corrects our substantially equivalent letter of January 16, 2003.

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.

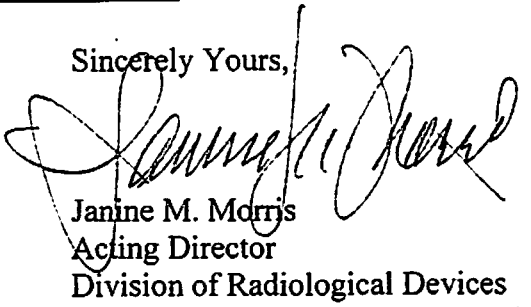
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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): K024200

Device Name: **Innova 2000 and Innova 2000 S (Mobile version)**

Indications for Use

The **Digital Fluoroscopic Imaging Systems** are indicated for use in diagnostic and interventional cardiac angiography and optionally, rotational cardiac angiography procedures of human anatomy. It is intended to replace image intensifier fluoroscopic systems in all diagnostic or interventional cardiac angiography procedures. They can be operated in a mobile as well as a fixed site environment.

(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)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K024200