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GE Healthcare

—510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: 5 June 2009

Submitter: GE Medical Systems, LLC
Doing business with GE Healthcare
3000 N. Grandview Blvd
Waukesha, WI 53188

Primary Contact Person: Alan Totah
Regulatory Affairs Director, Pre-market
GE Healthcare
Tel. : (262) -544-3424
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Secondary Contact Person: Philip Malca
Interventional Regulatory Affairs Director
GE Healthcare [GE Medical Systems SCS.]
Tel. : 33 1 30 70 42 07
Fax : 33 1 30 70 43 99

Device: Trade Name: Innova in Operating Room environment

Common/Usual Name: Innova 4100^{IQ}, 3100^{IQ}, 2100^{IQ}, 3131^{IQ}, 2121^{IQ}

Classification Names: System X-Ray, Angiographic

Product Code: MQB, IZI

Predicate Device(s): Innova 4100^{IQ}, 3100^{IQ}, 2100^{IQ}, 3131^{IQ}, 2121^{IQ}
K052412, K050489, K060259, K061163.

Device Description: The Innova series digital fluoroscopy systems labeling is modified to allow the use of this device in an Operating Room environment that is suitable for this device. The device is suitable for Interventional XRAY procedures (catheter, needle, Minimally Invasive Surgery) and can be used either in an Interventional Room (i.e. Cath Lab) or in an Operating Room Environment. The device is not suitable to do surgical procedures (ie. open surgery).

Intended 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. They are intended to replace fluoroscopic images obtained through image intensifier



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technology. These devices are not intended for mammography applications.

Technology The Innova in Operating Room environment employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence The subject device is of a comparable type and substantially equivalent to the unmodified Innova. For the purpose of comparison, the modified and unmodified devices are identical except for the labeling that is modified to allow the use of this device in the Operating Room environment that is suitable for it. This labeling modification to the Operator Manual does not adversely impact safety or effectiveness of the device.

The modified and unmodified devices are identical and have the same specifications. The risk analysis done on the product in an Operating Room environment did not raise new risk other than a potential foreseeable misuse in surgery. This has resulted in a labeling change of the operator manual. No further specification and testing were required.

There is no clinical testing for this modification since the intended use, indications for use and other product specifications do not change.

The following quality assurance measures were applied to the development of the system modification:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Summary of Clinical studies:

The subject of this Premarket submission, Innova in Operating room environment, did not require clinical studies to support substantial equivalence.

Conclusion GE Healthcare considers the Innova in Operating Room environment to be as safe and as effective as the predicate devices Innova, and its performance is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2009

Mr. Alan Totah
Regulatory Affairs Director - Premarket
GE HealthCare
3000 N. Grandview Blvd.
WAUKESHA WI 53188-1696

Re: K091658

Trade/Device Name: Innova in Operating Room Environment
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: June 5, 2009
Received: June 9, 2009

Dear Mr. Totah:

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 either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

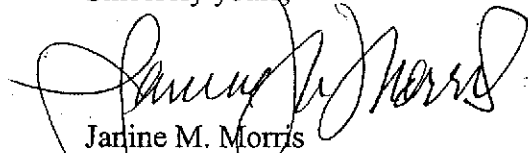
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/cdrh/mdr/> 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure



GE Healthcare

—510(k) Premarket Notification Submission

510(k) Number (if known): ~~not known~~ K091658

Device Name: Innova in Operating Room Environment

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. They are intended to replace fluoroscopic images obtained through image intensifier technology. These devices are not intended for mammography applications.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(Part 21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K091658