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K993037

GE Medical System
P.O. Box 414, W-709
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 Medical Systems
Tel. (414) 544-3894
Summary prepared: 31 August, 1999

Identification of Product: LCV+ Version 2
Classification Name: Solid State X-ray Imaging System
Manufacturer: GE Medical Systems S.A.-Europe
283, rue de la Minière
78530 Buc, France
Distributed by: GE Medical Systems, Milwaukee, WI

Marketed Devices: The **LCV+ Version 2** is substantially equivalent to the currently marketed **LC** cardiographic system (K890348), which complies with the same or equivalent standards and has the same intended uses. The digital sub-system, called **DL**, is substantially equivalent to the fluoroscopic digital equipment **DLX** (K926258 and K945459).

Device Description: The **LCV+ Version 2** is designed to perform fluoroscopic x-ray examinations. The detector is comprised of amorphous silicon with a cesium iodide scintillator. The resulting digital image can be sent through a fiber channel link to an acquisition equipment then to a network (using DICOM) for applications such as post-processing, printing, viewing and archiving. **LCV+ Version 2** consists of a cardiac monoplane positioner, a vascular table, an X-RAY system and a digital detector.

Materials: All construction and materials are compliant with UL 187 for the existing components and with UL2601, IEC 601-1 and collateral standards for the new components.

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Design: There are hardware and software redundancies to prevent single point failures that could cause unintended motion.

Energy Source: 360V to 480V AC, 50/60Hz.

Indications for Use: 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.

Comparison with: It is the opinion of GE Medical Systems that the **LCV+ Version 2** is of comparable type and substantially equivalent to an Advantx Cardiography System LC (K890348). The **LCV+ Version 2** presents no new safety concerns. This system will comply with the x-ray requirements of 21CFR as well as the safety requirements noted above.

Summary of Studies: Six (6) cardiologists from two (2) hospitals compared digital and image-intensifier recorded images from 31 pairs of patients, and found that the digital images had equivalent image capability.

Conclusions: GE considers the **LCV+ Version 2** to be equivalent with the predicate device. The **LCV+ Version 2** provides recorded fluoroscopic sequences that result in diagnostic capabilities equivalent to Image Intensifier images. The potential hazards, e.g., wrong measurements and misdiagnosis, are controlled by a risk management plan including:

- Hazard identification (Attachment 8)
- Risk evaluation (Attachment 8)
- Software Development and Validation Process (Attachment 7)
- External validations of paired sets of Image Intensifier image and digital images by two research hospitals to assess the diagnostic equivalence of the digital images.

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

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
P.O. Box 414, W-709
MILWAUKEE WI 53201

Re: K993037
Trade/Device Name: LCV+ Version 2 System (SSXI Fluoro Device)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: December 21, 1999
Received: December 22, 1999

Dear Dr. Kroger:

This letter corrects our substantially equivalent letter of February 14, 2000.

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.

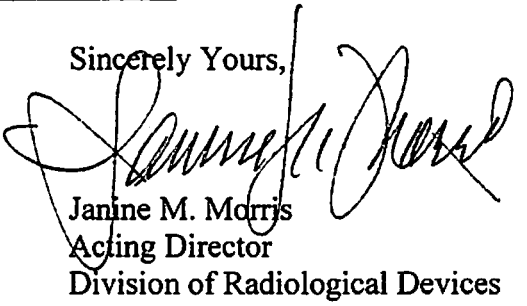
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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): K993037

Device Name: **LCV+ Version 2 System**

Indications for Use

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801-109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993037