K082960

OCT 17 2008

GE Healthcare

3000 N. Grandview Blvd. W-706
Waukesha, WI 53188

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

Submitter:

Name: GE Medical Systems, LLC (GE Healthcare)
Address: 3000 N. Grandview Blvd., W-1140
Waukesha, WI 53188

Contact: Steven Kachelmeyer
Pre-Market Regulatory Affairs Program Manager
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Date Prepared: August 11, 2008

PRODUCT IDENTIFICATION

Name: GE Xtream Injector Option

Classification Name: Accessory to Computed Tomography System
21CFR892.1750, 90-JAK

Manufacturer: GE Yokogawa Medical Systems
7-127 asahigaoka 4-chome
Hino-shi, Tokyo, Japan 191-8503

Future Production may also be accomplished at one of our other registered CT Manufacturing facilities.

Distributor: GE Medical Systems, LLC (GE Healthcare)
3000 N. Grandview Blvd.
Waukesha, WI 53188

Marketed Devices: The GE Xtream Injector Option is of a comparable type and substantially equivalent to currently marketed Toshiba Injector Synchronization Option (K061976), and Siemens CARE CONTRAST CT (K043087) and complies with the same or equivalent standards and have similar intended uses.

Predicate Device(s):

Toshiba Injector Synchronization Option (K061976)
Siemens CARE CONTRAST CT (K043087)

DEVICE DESCRIPTION

The GE Xtream Injector Option is a software and hardware option that is based on the CANopen Injector Interface Standard (CiA 425). The CANopen communication protocol allows integration and synchronization of the CT system with the injector. This option is an extension to the functionality of the existing GE CT systems and is designed to facilitate contrast-enhanced CT imaging by connecting the CT system and a 510(k) cleared compatible injector. The addition of this option to a GE CT Scanner simply implements an interface between the CT scanner and the injector following the defined communication standard. By utilizing this design standard, it will allow the Xtream Injector to operate any 510(k) cleared Injector that is compatible the CiA 425 standard. This option is being developed to be compatible with multiple GE CT scanners by adding the software and hardware components. As the software is integrated and verification is completed on the GE CT systems, a commercial introduction plan will be determined including appropriate Pre-Market Notifications for the CT systems.

Indications for Use:

The GE Xtream Injector Option is designed to facilitate contrast-enhanced Computed Tomography (CT) by providing a method for connection and communication to the CT system with a compatible injector. When used, it allows the user to synchronize the start of the CT scan and the injector by pressing one single start button at the CT scanner. The GE Xtream Injector Option is based on the protocol contained in the CiA425 standard, and allows approved injectors to operate with certain GE Healthcare CT scanners that have the modified software and hardware interface required for the CiA425 communication protocol. This device is only the communication protocol and bus interface needed to communicate with a 510(k) cleared Injector that is compatible with the CiA425 standard.

Comparison with Predicate:

The GE Xtream Injector Option follows the same design standard as the Toshiba Injector Synchronization Option (K061976) and Siemens CARE CONTRAST CT (K043087). The GE Xtream Injector Option uses similar operating principle as the Toshiba Injector Synchronization Option and the Siemens CARE CONTRAST CT, and is following the same design standard, as well as having similar indications for use. We believe the GE Xtream Injector Option is of comparable type and substantially equivalent to the currently marketed system listed above and complies with the same or equivalent standards and have the same intended uses.

Adverse Effects on Health:

Potential electrical, mechanical and radiation hazards are identified in a risk management summary (hazard analysis) and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.
- Adherence and certification to industry and international standards. (UL/CSA and IEC).

The device is designed and manufactured under the Quality System Regulations of 21CFR820.

Conclusions:

The GE Xtream Injector Option is an evolutionary modification to our existing cleared CT systems. It does not result in any new potential safety risks and performs as well as or better than devices currently on the market. GE considers the GE Xtream Injector Option to be equivalent to other marketed devices with similar indications for use and meeting similar standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2008

GE Medical Systems, LLC
% Mr. Daniel Lehtonen
Staff Engineer – Medical Devices
Intertek Testing Services NA, Inc.
2307 East Aurora Road, Unit B7
TWINSBURG OH 44087

Re: K082960
Trade/Device Name: GE Xtream Injector Option
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: October 2, 2008
Received: October 3, 2008

Dear Mr. Lehtonen:

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 such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082960

Device Name: GE Xtream Injector Option

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Prescription Use X (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082960