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GE Healthcare

K052839

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).

Date Prepared June 27 2005

Submitter

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3000 North Grandview Blvd.
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PRODUCT IDENTIFICATION

Name: CT Perfusion 4

Classification Name: Accessory to Computed Tomography System

Manufacturer: GE Medical Systems S.C.S
283, rue de la Minière
78533 Buc Cedex, FRANCE

Distributor: General Electric Medical Systems S.C.S, Buc, France.

Marketed Devices: The CT Perfusion 4 is substantially equivalent to the devices listed below:

Model:	CT Perfusion 2
Manufacturer:	GE Medical Systems S.C.S, Buc, France
510(k) #:	K010042

Device Description:

CT Perfusion 4 is an image analysis software package that allows the evaluation of dynamic CT data following an injection of a compact bolus of contrast material, generating information with regards to changes in image intensity over time. It provides a quick and reliable assessment of the type and

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extent of perfusion disturbances by providing qualitative and quantitative information on various perfusion related parameters.

The results are displayed in a user-friendly graphic format as parametric images (single image calculated from a set of time course images at a single location).

Indications for Use:

CT perfusion 4 is an image analysis software package that allows the user to produce dynamic image data and to generate information with regard to changes in image intensity over time. It supports the analysis of CT Perfusion images, obtained by cine imaging (in the head and body) after the intravenous injection of contrast, in calculation of the various perfusion-related parameters (i.e. regional blood flow, regional blood volume, mean transit time and capillary permeability). The results are displayed in a user-friendly graphic format as parametric images.
This software will aid in the assessment of the extent and type of perfusion, blood volume and capillary permeability changes, which may be related to stroke or tumor angiogenesis and the treatment thereof.

Comparison with Predicate:

CT Perfusion 4 images as compared with the CT Perfusion 2 device are obtained by CT scanning after an injection of contrast media. CT Perfusion 4 is a software post-processing device and as such does not affect the dosage characteristics or the imaging performance of GEMS CT scanners. The algorithms used to calculate the perfusion parameters are similar to CT Perfusion 2 device. The functional features of the CT Perfusion 4 software package are substantially equivalent to that of the following device:

Device Name	FDA Clearance Number
CT Perfusion 2	K010042

Adverse Effects on Health:

The potential hazards are identified in a risk management summary (hazard analysis) and are controlled by:

- Software Development, Validation and Verification Process to ensure performance to specifications, Federal Regulations and user requirements.
- Adherence to industry and international standards.

Conclusions:

CT Perfusion 4 does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the CT Perfusion 4 to be equivalent to those of CT Perfusion 2 (K010042).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 2006

GE Healthcare
c/o Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 017190

Re: K052839
Trade/Device Name: CT Perfusion 4
Regulation Number: 21 CFR §892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: February 14, 2006
Received: February 15, 2006

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 (Premarket Approval), 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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
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): K052839

Device Name: CT Perfusion 4

Indications for Use:

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This software will aid in the assessment of the extent and type of perfusion, blood volume and capillary permeability changes, which may be related to stroke or tumor angiogenesis and the treatment thereof.

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)

David A. Lieberman

(Division Sign-Off)

Division of [illegible]

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