K993791

NOV 24 1999

GE Medical Systems
P.O. Box 414, W-709
Milwaukee, WI 53201 USA

CT PERFUSION
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 Program Manager
Telephone: (414) 544-3894
Date Prepared: October 21, 1999

Identification of Product:

Name :	CT Perfusion Option
Manufacturer :	General Electric Medical Systems 283, rue de la Miniere 78533 Buc Cedex, FRANCE
Distributor :	General Electric Medical Systems, Milwaukee, WI

Marketed Devices:

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

Model:	Functool
Manufacturer:	General Electric Medical Systems, Milwaukee, WI
510(k) #:	K960265
Model:	CT 9800 Regional Cerebral Blood Flow
Manufacturer:	General Electric Medical Systems, Milwaukee, WI
510(k) #:	83K0739

Device Description:

CT Perfusion is an image analysis software package that allows the user to process dynamic image data and to generate information with regard to changes in image intensity over time. It supports the analysis of CT Perfusion images and displays the analysis data in a user friendly graphic format and as parametric (single image that is calculated from a set of time course images at a single location) images.

Application examples include:

° characterization of the amount of blood present in a local region.
° provides the volume of blood that flows through a cerebral circulation region.
° returns the average transit time.

° characterizes image intensity increase during a dynamic process.
° allows selection of any time-series or "dynamic" data set.

Indications for Use :
CT Perfusion 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 after the injection of contrast and to calculate the various perfusion related parameters (ie: regional cerebral blood flow, regional cerebral blood volume, time to peak). The results are displayed in user-friendly graphic format as parametric images. This software runs on the Advantage Workstation (AW) platform and will aid physicians in the assessment of the extent and type of brain perfusion disturbances.

Comparison with Predicate:
CT Perfusion supports the analysis of perfusion CT images and the display of the data in user-friendly graphs and as parametric images. This package is substantially equivalent to the following devices:

Device Name	FDA Clearance Number
GEMS Functool	K960265
GEMS CT 9800 Regional Cerebral Blood Flow	83K0739

CT Perfusion images as compared with the CT 9800 Regional Cerebral Blood Flow device are obtained by CT scanning after an injection of contrast media. CT Perfusion 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 the GEMS CT 9800 Regional Cerebral Blood Flow device.

Conclusions :
The CT Perfusion option provides processing capability for dynamic image data and to the ability to generate information with regard to changes in image intensity over time. The potential hazards are controlled by a risk management plan including:

- a Hazard Analysis/Risk Management Summary
- a Software Development and Validation Process
- a Software Verification Plan

This product provides images comparable to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 1999

General Electric Medical Systems
c/o Reiner Krumme
TUV Rheinland of North America, Inc.
12 Commerce Road
Newton, CT 06570

Re: K993791
CT Perfusion Option
Dated: November 4, 1999
Received: November 9, 1999
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Krumme:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: CT Perfusion

Indications for Use

CT Perfusion 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 after the injection of contrast and to calculate the various perfusion related parameters (ie: regional cerebral blood flow, regional cerebral blood volume, time to peak). The results are displayed in user-friendly graphic format as parametric images. This software runs on the Advantage Workstation (AW) platform and will aid physicians in the assessment of the extent and type of brain perfusion disturbances.

(PLESE 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. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993791