K982536

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ATTACHMENT 8

510(K) SUMMARY

Perfusion CT Software Package for the SOMATOM CT Systems

Submitted by:

Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830

November 23, 1998

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Contact Person:

Ms. Malgorzata Stanek
Phone: (732) 321-3950 Fax: (732) 321-4841

2. Device Name and Classification:

Trade Name:	Perfusion CT Software Package
Classification Name:	Computed Tomography X-ray System
CFR Section:	21 CFR §892.1750, Class II
Device Code:	90JAK

3. Substantial Equivalence:

The Perfusion CT software package designed for post processing images that have been continuously acquired with computed tomography (CT) imaging systems meeting certain minimal requirements (i.e. Siemens SOMATOM Plus 4, SOMATOM AR.STAR, SOMATOM Classic), is substantially equivalent to the following devices:

SIEMENS Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Xenon CT	K875088	6/26/88
Dynamic CT option (Somatom AR)	K910859	5/15/91
(Somatom Plus)	K880965	3/28/88

Perfusion CT images, as compared with Xenon CT images and Dynamic CT images, are acquired in the same manner: injection of contrast media followed by CT scanning. In addition, like the predicate devices, Perfusion CT is a post-processing evaluation package and as such do not affect the dosage characteristics or the imaging performance parameters of the Siemens CT scanners.

4. **Device Description:**
Perfusion CT is a post-processing software package which runs on an Intel-based PC platform designed to post-process images acquired with SOMATOM CT scanners which meet certain minimal requirements (i.e. Siemens SOMATOM Plus 4, SOMATOM AR.STAR, SOMATOM Classic). It is a package containing evaluation software that supports the evaluation of Dynamic CT data gathered after the injection of a compact bolus of contrast media, where the contrast media acts as a pure intravascular tracer.

Perfusion CT calculates the parameters related to brain perfusion and cerebral blood flow (CBF) using a simple linear relationship between the detected change of signal and the actual concentration of contrast media.

5. **Intended Use of the Device:**
Perfusion CT is an application software package that permits cerebral perfusion imaging based on dynamic CT images continuously acquired after the injection of contrast. The package allows visualization of apparent blood flow in brain tissue and pictorially illustrates perfusion related parameters (i.e. relative cerebral blood flow, relative cerebral blood volume, time to peak). By generating images of cerebral blood flow (CBF), cerebral blood volume (CBV), and local bolus timing (i.e. time to peak) from one set of dynamic CT images, Perfusion CT aids the physician in the assessment of the type and extent of cerebral perfusion disturbances. The software package also allows the calculation of mirrored regions of interest and the visual inspection of time density curves.

6. **Summary of Technological Characteristics of the Device Compared to the Predicate Device:**
The Perfusion CT software package has the same technological characteristics as the predicate Xenon CT and Dynamic CT, except that Perfusion CT provides the user with additional post-processing information related to brain perfusion. They both require the use of a contrast medium, rapid image scanning, and the intervention of a physician in setting necessary parameters and in assessing resultant images.

7. **Clinical Studies and Conclusion:**
Clinical studies were carried out in Europe to collect cerebral images from individuals with suspected local ischemia. The results from the studies showed that the Perfusion CT post-processing software package is useful in aiding physicians in diagnosing ischemia.

Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 1998

Malgorzata Stanek
Technical Specialist
Regulatory Submissions
Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830

Re: K982536
Perfusion CT Software Package
Dated: November 17, 1998
Received: November 18, 1998
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Stanek:

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 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 9

INDICATIONS FOR USE

510(k) Number (if known): K982536
Device Name: Perfusion CT Software Package

Indications for Use:

Perfusion CT is an application software package that permits cerebral perfusion imaging based on dynamic CT images continuously acquired after the injection of contrast. The package allows visualization of apparent blood flow in brain tissue and pictorially illustrates perfusion related parameters (i.e. relative cerebral blood flow, relative cerebral blood volume, time to peak). By generating images of cerebral blood flow (CBF), cerebral blood volume (CBV), and local bolus timing (i.e. time to peak) from one set of dynamic CT images, Perfusion CT aids the physician in the assessment of the type and extent of cerebral perfusion disturbances. The software package also allows the calculation of mirrored regions of interest and the visual inspection of time density curves.

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982536