DEC 15 2004

510(K) SUMMARY
FOR
SIEMENS CARE CONTRAST CT

Submitted by:

Siemens Medical Solutions, Inc.
51Valley Stream Parkway
Malvern, PA 19355

November 3, 2004

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

1. **Contact Person:**

Ms. Debbie Peacock
Technical Specialist, Regulatory Affairs
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway E50
Malvern, PA 19355
Phone: (610) 448-1773
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Email: debra.peacock@siemens.com

2. **Device Name and Classification**

Product Name:	SOMATOM CARE Contrast CT
Classification Name:	Accessory to Computed Tomography System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90 JAK

3. **Importer/Distributor Establishment:**

Registration Number: 2240869
Siemens Medical Solutions, Inc. USA
51 Valley Stream Pkwy
Malvern, PA 19355

Manufacturing Facility:

Siemens AG
Wittelsbacherplatz 2
DE- 80333 Muenchen
Germany

4. Substantial Equivalence

The CARE Contrast CT package, addressed in this premarket notification, is substantially equivalent to the following commercially available software package:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Siemens SOMATOM Emotion 6 (P10F)	K023687	11/22/2002
Siemens SOMATOM Sensation 64 (P30F)	K040665	04/02/2004
Siemens SOMATOM Sensation Open (P30L)	K040577	03/22/2004

5. Device Description

CARE Contrast CT for the SOMATOM CT Systems includes both hardware and software components. *CARE Contrast CT* is an optional extension to the functionality of Siemens SOMATOM Emotion and Sensation CT scanners and is designed to facilitate contrast enhanced CT examinations by connecting CT and injector. The addition of the CARE Contrast CT option to the SOMATOM scanners simply implements an interface between CT scanners and an injector. *CARE Contrast CT* is based on the future standard for the communication between CT and injector.

6. Indications for Use

CARE Contrast CT is designed to facilitate contrast enhanced CT examinations by connecting CT and injector. If *CARE Contrast CT* is activated, the contrast-enhanced examination can be started by pressing one single start button, either at the CT scanner or at the injector. *CARE Contrast CT* is based on the future standard for the communication between CT and injector.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2004

Ms. Debbie Peacock
Technical Specialist
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway
MALVERN PA 19355

Re: K043087
Trade/Device Name: CARE Contrast CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray sytem
Regulatory Class: II
Product Code: 90 JAK
Dated: November 3, 2004
Received: November 8, 2004

Dear Ms. Peacock:

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/dsma/dsmamain.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): K043087

Device Name: **CARE Contrast CT**

CARE Contrast CT is designed to facilitate contrast enhanced CT examinations by connecting CT and injector. If *CARE Contrast CT* is activated, the contrast enhanced examination can be started by pressing one single start button, either at the CT scanner or at the injector. *CARE Contrast CT* is based on the future standard for the communication between CT and injector.

(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. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043087