APR - 2 2004

# 510(K) SUMMARY
FOR
SOMATOM PROJECT P30F

Submitted by:
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway
Malvern, PA 19355

March 1, 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. Nealie Hartman
Technical Specialist, Regulatory Affairs Submissions
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway J-15
Malvern, PA 19355
Phone:(601) 448-1769
Fax: (601) 448-1787

2. **Device Name and Classification**

| | |
|---|---|
| Product Name: | SOMATOM Project P30F |
| Classification Name: | Computed Tomography System |
| Classification Panel: | Radiology |
| CFR Section: | 21 CFR §892.1750 |
| Device Class: | Class II |
| Product Code: | 90 JAK |

3. **Substantial Equivalence:**

Siemens SOMATOM P30F Computed Tomography X-ray systems, configured with software version SOMARIS/5 is substantially equivalent to the following medical device in commercial distribution:

| *Predicate Device Name* | *FDA Clearance Number* | *FDA Clearance Date* |
|---|---|---|
| Siemens SOMATOM P30 | K013522 | 11/07/2001 |

**4. Device Description:**

The Siemens SOMATOM P30F is a whole body X-ray computed tomography systems, which features a continuously rotating tube-detector system and functions according to the fan beam principle. The system software is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation.

**5. Indications for Use:**

The SOMATOM P30 is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angels or spiral planes* taken at different angles.

(*spiral planes: the axial planes resulted from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

**6. General Safety and Effectiveness Concerns:**

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Nealie Hartman
Technical Specialist, Regulatory
Affairs Submissions
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway J-15
MALVERN PA 19355

Re: K040665
Trade/Device Name: SOMATOM Project P30F
(Sensation 64/Sensation Cardiac)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography
x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: March 1, 2004
Received: March 4, 2004

Dear Ms. Hartman:

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 the letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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

# SECTION 3
# INDICATION FOR USE

510(k) Number (if known): K040665

Device Name: **SOMATOM Project P30F**

**(Sensation 64 / Sensation Cardiac)**

The Siemens SOMATOM P30F systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

(*spiral planes: the axial planes resulted from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

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

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

Prescription Use (Per 21 CFR §801.109)

OR Over-The-Counter Use

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040665