510(k) Summary

For

SOMATOM Definition AS Open

MAR - 4 2011

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

September 25, 2010

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. General Information

Importer / Distributor
Siemens Medical Solutions, Inc.
51 Valley Stream Parkway, E-50
Malvern, PA 19355
Establishment Registration Number
2240869

Manufacturing Site
SIEMENS AG Sector Healthcare
Siemens Straße 1
D-91301 Forchheim

2. Contact Person:

Mrs. Alicia Bustos-Juergensen
Technical Specialist, Regulatory Affairs Submissions
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway E-50
Malvern, PA 19355-1406
Phone:(610) 448-4056 Fax: (610) 448-1778

3. Device Name and Classification

Product Name:	SOMATOM Definition AS
Propriety Trade Name:	SOMATOM Definition AS Open
Classification Name:	Computed Tomography X- ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90 JAK

4. Device Description

The Siemens SOMATOM Definition AS Open is a Computed Tomography X- ray Systems, which features a continuously rotating tube-detector system and functions according to the fan beam principle.

This system is a modified version of the cleared Somatom Definition AS/AS+ (K081022). The modification features a larger gantry bore from the original Definition AS, In addition, the gantry tilt accuracy is improved and a new HD FoV, will help provide an optimized solution for radiation treatment planning.

5. Intended Use

The SOMATOM Definition AS Open 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 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.)

6. Substantial Equivalence:

Siemens SOMATOM Definition AS Open Computed Tomography X-ray system, configured with software version SOMARIS/7 is substantially equivalent to the following medical device in commercial distribution:

Predicate Device Name	FDA Clearance Number	FDA Clearance Date
Siemens SOMATOM Definition AS/AS+	K081022	06/05/2008

7. Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Device

SOMATOM Definition AS Open is a modified SOMATOM Definition AS, which offers a larger gantry bore of 80 cm. It uses a modified tube collimator, adapted to the geometry of the 80 cm gantry bore

The Data Measurement System (DMS) of SOMATOM Definition AS Open is identical to the 32 row detector layout of SOMATOM Definition AS; UHR comb is not available for SOMATOM Definition AS Open.

SOMATOM Definition AS Open is designed with the mechanical accuracy necessary to provided data that can be used for Radiation Therapy Planning (RTP) by RTP systems.

8. General Safety and Effectiveness Concerns

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner. Several safety features including visual and audible warnings are incorporated into the system design. In addition the Somatom Definition AS Open is continually monitored, and if an error occurs, the system functions will be blocked and an error message will be displayed.

Furthermore the operators are health care professionals familiar with and responsible for the X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

9. Conclusion as to Substantial Equivalence

The Somatom Definition AS Open is intended for the same indications for use as the predicate Somatom Definition AS/AS+. The Somatom Definition AS Open is substantially equivalent to the Definition AS/AS+ with changes to the gantry opening, improved FoV and improvements to the mechanical accuracy of the gantry tilt system as required when used for Radiation Therapy Planning.
The portfolios of accessories are the same as with the predicate Somatom Definition AS/AS+ to compliment the needs of the CT suite. It is Siemens opinion, that the Somatom Definition AS Open is substantially equivalent to the Somatom Definition AS/AS+.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Alicia Bustos-Juergensen
Technical Specialist Regulatory Affairs
Siemens Healthcare (Siemens Medical Solutions USA, Inc.)
51 Valley Stream Pkwy
MALVERN PA 19355

MAR - 4 2011

Re: K103127
Trade/Device Name: Somatom Definition AS Open
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: February 11, 2011
Received: February 14, 2011

Dear Ms. Bustos-Juergensen:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K103127

Device Name: ***Somatom Definition AS Open***

Indications for Use:

The Siemens SOMATOM Definition AS Open 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.)

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Patel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K103127