510(K) SUMMARY

FOR

**SOMATOM DEFINITION** Flash (with Stellar Detector)

Submitted by:

Siemens Medical Solutions USA, Inc.

51 Valley Stream Parkway

Malvern, PA 19355

Novemberr 9, 2011

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:**

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

2. **Device Name and Classification**

| | |
|---|---|
| Product Name: | SOMATOM Definition Flash (with Stellar Detector) |
| Propriety Trade Name: | SOMATOM Definition Flash |
| Classification Name: | Computed Tomography X- ray System |
| Classification Panel: | Radiology |
| CFR Section: | 21 CFR §892.1750 |
| Device Class: | Class II |
| Product Code: | 90 JAK |

**3. Substantial Equivalence:**

Siemens SOMATOM Definition Flash (with Stellar Detector) Computed Tomography X-ray system, configured with software SOMARIS/7 is substantially equivalent to the following medical device in commercial distribution:

| *Predicate Device Name* | *FDA Clearance Number* | *FDA Clearance Date* |
|---|---|---|
| Siemens SOMATOM FLASH DS | K082220 | 10/10/2008 |

**4. Device Description:**

The Siemens SOMATOM Definition Flash (with Stellar Detector) is a Computed Tomography X- ray System, which features two continuously rotating tube-detector systems 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.

The SOMATOM Definition Flash (with Stellar Detector) produces CT images in DICOM format, which can be used by post-processing applications commercially distributed by Siemens and other vendors.

The computer system delivered with the CT scanner is able to run such post processing applications optionally.

**5. Indications for Use:**

The Siemens SOMATOM Definition Flash (with Stellar Detector) 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.

In addition the SOMATOM Definition Flash (with Stellar Detector) is able to produce additional image planes and analysis results by executing optional post-processing features, which operate on DICOM images.

The images and results delivered by the system can be used by a trained physician as an aid in diagnosis.

(*spiral planes: the axial planes resulting 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 during 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
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

DEC 2 9 2011

Ms. Kim Mangum
Regulatory Affairs Technical Specialist
Siemens Medical Solutions, USA Inc.
51 Valley Stream Parkway
Mail Code D02
MALVERN PA 19355

Re: K113342
Trade/Device Name: SOMATOM Definition Flash (with Stellar Detector)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: November 9, 2011
Received: November 14, 2011

Dear Ms. Mangum:

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, Sc.D.
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): _____

Product Name: ***SOMATOM Definition Flash (with Stellar Detector)***

**Indications for Use:**

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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)

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

Mary S Pastel

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

510(k) K113342