



Food and Drug Administration
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Silver Spring, MD 20993-0002

Siemens Medical Solutions USA, Inc.
% Ms. Eve Davis
Regulatory Affairs Specialist
51 Valley Stream Parkway
MALVERN PA 19355

May 18, 2015

Re: K150785
Trade/Device Name: syngo.CT Dental
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 20, 2015
Received: March 25, 2015

Dear Ms. Davis:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. Behind the signature, there is a faint, semi-transparent watermark of the FDA logo.

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K150785

Device Name
Syngo.CT Dental

Indications for Use (Describe)

Syngo.CT Dental is post processing image analysis software for CT volume data sets that has been acquired continuously with computed tomography (CT) systems. The software provides the following digital image processing and visualization tools:

Basic reading tools: Multiplanar Reconstruction (MPR), Maximum Intensity Projection (MIP), Volume Rendering Technique (VRT), Minimal Intensity Projection (MinIP)

Basic geometric measurement tools: distance line, polyline, marker, arrow, angle

Basic HU measurement tools: Pixel lens, ROI Circle, ROI polygonal, ROI freehand, VOI sphere, VOI freehand

Dedicated dental visualization tools: Dental panoramic views (curved MPRs) and dental paraxial views (cross-section MPRs) that are calculated based on a manually defined centerline.

A tool to manually outline the mandibular canal.

A tool that allows paraxial and panoramic result images to be saved as dental range series.

True Size (1:1) printing of panoramic and paraxial images to allow anatomy to be printed in its actual size on the film sheet.

The specific visualization of panoramic and paraxial views of the dental structures facilitates viewing, manual identification, and marking of dental pathologies and anatomy (for example, the position of the mandibular canal that needs to be preserved during dental interventions, such as dental (implant) surgery). Reporting and documentation of results is facilitated by the creation of ranges and snapshots, True Size (1:1) printing on DICOM printers, and by the use of a reporting tool.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary: *syngo*.CT Dental

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

Date Prepared: May 11, 2015

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. General Information

Importer/Distributor:

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

Establishment Registration Number: 2240869

Manufacturing Site:

Siemens AG
Medical Solutions
Siemens Str. 1
D-91301 Forchheim, Germany
Owner/Operator No.: 8010024
Establishment Registration No: 3004977335

2. Contact Person:

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3. Device Name and Classification

| | |
|------------------------------|----------------------------------|
| Product Name: | <i>syngo</i> .CT Dental |
| Propriety Trade Name: | <i>syngo</i> .CT Dental |
| Classification Name: | Computed Tomography X-ray System |
| Classification Panel: | Radiology |
| CFR Section: | 21 CFR §892.1750 |
| Device Class: | Class II |
| Product Code: | JAK |

4. Legally Marketed Predicate Device

| | |
|-----------------------------------|---|
| Trade Name: | Dental CT Option |
| 510(k) #: | K913996 |
| Clearance Date: | November 22, 1991 |
| Classification Name: | Computed Tomography X-ray System |
| Classification Panel: | Radiology |
| Classification Regulation: | 21 CFR § 892.1750 |
| Device Class: | II |
| Product Code: | JAK |
| Recall Information: | This predicate device has not been the subject of any design related recalls. |

Reference Device

| | |
|-----------------------------------|--|
| Trade Name: | <i>syngo</i> .via |
| 510(k) #: | K123375 |
| Clearance Date: | November 20, 2012 |
| Classification Name: | System, Image Processing, Radiological |
| Classification Panel: | Radiology |
| Classification Regulation: | 21 CFR § 892.2050 |
| Device Class: | II |
| Product Code: | LLZ |

5. Device Description:

syngo.CT Dental is post-processing image analysis software for computed tomography volume data sets that combines basic and advanced visualization that can be used in pre-surgical planning for dental operations, such as the planning of dental implant surgery. *syngo*.CT Dental contains image processing tools that allow for easy viewing and manual identification and marking of dental anatomy and pathologies by a physician.

The following modifications have been made to the previously cleared predicate device K913996, clearance date November 22, 1991 and are the subject of this 510(k) submission:

1. A new software version SOMARIS/8 VB10 which supports the following:
 - migration of Dental Option for SOMATOM CT System to the *syngo*.via client server platform (*syngo*.via platform cleared in K123375)
 - Name change to *syngo*.CT Dental
 - Basic Reading Tools – addition of VRT and MinIP
 - Basic Geometric Measurement Tools – addition of polyline, arrow, and angle
 - Basic HU Measurement Tools – addition of Pixel lens and VOI

- storage of Panoramic and Paraxial Range images to the *syngo.via* database
 - updated graphical user interface
 - Archiving/storage on CD-R and DVD
- 2. An extended, more descriptive Indication for Use statement to include details of device functionality

6. **Indications for Use:**

syngo.CT Dental is post processing image analysis software for CT volume data sets that has been acquired continuously with computed tomography (CT) systems. The software provides the following digital image processing and visualization tools:

- Basic reading tools: Multiplanar Reconstruction (MPR), Maximum Intensity Projection (MIP), Volume Rendering Technique (VRT), Minimal Intensity Projection (MinIP)
- Basic geometric measurement tools: distance line, polyline, marker, arrow, angle
- Basic HU measurement tools: Pixel lens, ROI Circle, ROI polygonal, ROI freehand, VOI sphere, VOI freehand
- Dedicated dental visualization tools: Dental panoramic views (curved MPRs) and dental paraxial views (cross-section MPRs) that are calculated based on a manually defined centerline.
- A tool to manually outline the mandibular canal.
- A tool that allows paraxial and panoramic result images to be saved as dental range series.
- True Size (1:1) printing of panoramic and paraxial images to allow anatomy to be printed in its actual size on the film sheet.

The specific visualization of panoramic and paraxial views of the dental structures facilitates viewing, manual identification, and marking of dental pathologies and anatomy (for example, the position of the mandibular canal that needs to be preserved during dental interventions, such as dental (implant) surgery). Reporting and documentation of results is facilitated by the creation of ranges and snapshots, True Size (1:1) printing on DICOM printers, and by the use of a reporting tool.

7. **Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:**

syngo.CT Dental software package has the same intended use and operating principle as the predicate device, Dental CT Option (K913996, clearance date 11/22/1991). *syngo*.CT Dental device is a post-processing application that will operate on the multi-user *syngo.via* client/server platform.

syngo.CT Dental does not have significant changes in technological characteristics when compared to the predicate device. The indications for use and fundamental scientific technology are similar. The subject device and predicate device are the same in regards to:

- Anatomic Region
- Dedicated Dental Visualization Tools
- Outlining of the Mandibular Canal
- Reporting (True Size printing)
- DICOM compatible Communication

The subject device and the reference device (K123375) are the same in regards to:

- Basic Reading Tools (VRT, MinIP)
- Basic Geometric Measurement Tools (polyline, arrow, angle)
- Basic HU Measurement Tools (Pixel Lens, ROI, Circle, ROI polygonal, ROI freehand, VOI sphere, VOI freehand)

The following table shows the differences in technological characteristics between the subject device and the predicate device.

| Differences in Technological Characteristics of the Subject Device Compared to the Predicate Device | | | |
|--|--|--|---|
| Feature | Subject Device <i>syngo</i>.CT Dental | Predicate Device Dental CT Option (K913996) | Comparison |
| Basic Reading Tools | MPR, MIP, VRT, MinIP | MPR, MIP | Volume Rendering Technique (VRT) and Minimal Intensity Projection (MinIP) reading is available on the subject device with the migration to the <i>syngo</i> .via platform (K123375). Verification and Validation testing supports this modification. |
| Basic Geometric Measurement Tools | Manual measurement of distance line, polyline, review marker, arrow and angle | Manual measurement of distance line and review marker | Manual measurement of polyline, arrow, and angle are available on the subject device with the migration to the <i>syngo</i> .via platform (K123375). Verification and Validation testing supports this modification. |
| Basic HU Measurement Tools | Manual measurement of pixel lens, ROI circle, ROI polygonal, ROI freehand, VOI sphere, and VOI | ROI | Manual measurement of Pixel Lens, Region of Interest (ROI) Circle, ROI polygonal, ROI freehand, Volume of Interest (VOI) sphere, and VOI freehand are available on the subject device with the migration to the <i>syngo</i> .via platform (K123375). |

| Differences in Technological Characteristics of the Subject Device Compared to the Predicate Device | | | |
|---|---|---|--|
| Feature | Subject Device <i>syngo</i> .CT Dental | Predicate Device Dental CT Option (K913996) | Comparison |
| | freehand | | Verification and Validation testing supports this modification. |
| Panoramic and Paraxial Range Saving | Generated images are stored to the <i>syngo</i> .via database | Generated images are stored on magnetic disks | The image results will now be saved to the <i>syngo</i> .via database, however the purpose of those images remains the same. From the <i>syngo</i> .via database, the images can be further distributed to either the PACS or to disk. Verification and Validation testing supports this modification. |
| Workstation, Operating Software Platform | <i>syngo</i> .via: Windows XP, Windows Vista or Windows 7 systems. The <i>syngo</i> .via framework is a multiuser HW/SW architecture with client/server support. | <i>syngo</i> classic: SOMATOM CT standard HW/SW | Siemens <i>syngo</i> .via platform is a client/server multi-user framework and is a further development of <i>syngo</i> classic. It runs on updated Windows systems, and can support multiple users. |
| User Interface | <i>syngo</i> .via based GUI | SOMATOM CT Workstation | The user interface has been adapted from <i>syngo</i> Classic to the current <i>syngo</i> .via framework. Verification and Validation testing supports this modification. |
| Archiving / Storing | MOD, CD-R, film; DVD | MOD, film | The subject device has the additional ability to store images on CD-R or DVD as compared to the predicate. Verification and Validation testing supports this modification. |

8. Nonclinical Testing:

Nonclinical tests were conducted for *syngo*.CT Dental during product development. The modifications described in this premarket notification were supported with verification and validation testing. Siemens claims conformance to the following five safety and performance standards for *syngo*.CT Dental:

| Title of Standard | Reference Number and Date | Publication Date | Standards Development Organization |
|---|---------------------------------|------------------|------------------------------------|
| Digital Imaging and Communications in Medicine (DICOM) Set | PS 3.1 – 3.18 | 03/16/2012 | NEMA |
| Medical device software – Software life cycle processes | 62304 First edition 2006-05 | 08/20/2012 | IEC |
| Medical devices – Application of risk management to medical devices | 14971 Second Edition 2007-03-01 | 08/20/2012 | ISO |
| <u>Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance -- Collateral Standard: Usability</u> | 60601-1-6 Edition 3.0 2010-01 | 1/30/2014 | IEC |
| Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems, edition 1.1 | 60601-1-4:2000, Consol. Ed. 1.1 | 09/08/2009 | IEC |

Verification and Validation

This submission contains performance data to demonstrate continued conformance with special controls for medical devices containing software. Integration and functional tests were conducted for *syngo*.CT Dental during product development.

Software Documentation for a Moderate Level of Concern software per FDA’s Guidance Document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued on May 11, 2005 is also included as part of this submission. The test results show that all of the software specifications have met the acceptance criteria.

The risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results support that all of the software specifications have met the acceptance criteria. Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

Siemens conforms to the Cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient. It is the hospital’s responsibility to comply with IEC 8001-1-2010.

Summary

Performance tests were conducted to test the functionality of the subject device, *syngo*.CT Dental. Results of all conducted testing were found acceptable in supporting the claim of substantial equivalence.

9. 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.

10. Conclusion as to Substantial Equivalence

The modifications made to the predicate device add basic reading and viewing functionality. There is no new clinical functionality.

The predicate device was cleared based on non-clinical supportive information. The subject device non-clinical data supports the safety of the software with verification and validation testing. Verification and validation testing demonstrates that *syngo*.CT Dental performs as intended. The non-clinical test data demonstrates that *syngo*.CT Dental device performance is comparable to the predicate device that is currently marketed for the same intended use.

In summary, Siemens is of the opinion that the *syngo*.CT Dental does not introduce any new potential safety risk and is substantially equivalent to and performs as well as the predicate devices.