Siemens Medical Solutions USA, Inc.
% Tabitha Estes
Regulatory Affairs Specialist
810 Innovation Drive
KNOXVILLE TN 37932

July 22, 2021

Re: K203411
Trade/Device Name: syngo.CT Skull Unfolding
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: June 18, 2021
Received: June 21, 2021

Dear Tabitha Estes:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203411

Device Name
syngo.CT Skull Unfolding

Indications for Use *(Describe)*
syngo.CT Skull Unfolding provides curved MIP images of skull and brain surface for visual assessment by a radiologist.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

FOR

SYNGO.CT SKULL UNFOLDING K203411

I. Identification of the Submitter

Importer/Distributor
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355

Establishment Registration Number
2240869

Manufacturing Site
Siemens Healthcare GmbH
Siemensstr 1
D-91301 Forchheim, Germany

Establishment Registration Number
3004977335

Submitter Contact Person:
Tabitha Estes
Regulatory Affairs Specialist
Siemens Medical Solutions, Inc. USA
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Knoxville, TN 37932
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Email: tabitha.estes@siemens-healthineers.com

Alternate Contact:
Alaine Medio

II. Device Name and Classification

Product Name:	syngo.CT Skull Unfolding
Propriety Trade Name:	syngo.CT Skull Unfolding
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

III. Predicate Device

Predicate Device:

Trade Name:	syngo.CT Bone Reading
510(k) Number:	K123584
Clearance Date:	03/12/2013
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

Reference Device:

Trade Name:	syngo.via VB40
510(k) Number:	K191040
Clearance Date:	05/16/2019
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

IV. Device Description

This section describes the technical features and workflow for subject device syngo.CT Skull Unfolding. syngo.CT Skull Unfolding is image analysis software for CT volume data sets which has been continuously acquired with computed tomography (CT) imaging systems. syngo.CT Skull Unfolding provides advanced visualization of the skull and brain surface for easy manual identification, marking and reporting of pathologies such as skull fractures and hematomas. It receives images from a hosting application and returns DICOM images to a hosting application, which can display the results within its user interface. The device does not mark, highlight, or direct users' attention to a specific location in the original image.

V. Indications for Use

syngo.CT Skull Unfolding provides curved MIP images of skull and brain surface for visual assessment by a radiologist.

VI. Comparison of Technological Characteristics with the Predicate Device

The differences and similarities between the above referenced predicate device are listed at a high-level in the following table:

Features	Subject Device Siemens syngo.CT Skull Unfolding	Predicate Device Siemens syngo.CT Bone Reading	Reference Device Siemens syngo.via VB40	Summary
Advanced Visualization	Unfolded view of the skull	Unfolded view of the ribs	Advanced visualization of Curved spine ranges	**Comparable** Both subject and predicate device provide unfolded views of the respective anatomy as advanced visualization
Visualization Techniques	Curved maximum intensity projection (MIP)	Curved multiplanar reconstruction (MPR) and other filter techniques (multiplanar reconstruction (MPR) thin/thick, maximum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT))	Curved multiplanar reconstruction (MPR) and other filter techniques (multiplanar reconstruction (MPR) thin/thick, maximum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT))	**Similar** Both, the subject device, and the reference device provide curved visualizations. The subject device represents a subset of functionalities.
Localization of Anatomy	Head localization via anatomical range "Head Orbitomeatal" based on landmark detection	Spine Localization via spine range based on landmark detection	Anatomical auto views and anatomical ranges (by selecting anatomical presets, e.g. "Head Orbitomeatal") based on landmark detection.	**Similar** The subject device uses the same anatomical range "Head Orbitomeatal" of the reference device. For both subject and predicate device, the fundamental technology is the same but different landmarks are used due to different anatomy.
Bone Segmentation	Thresholding based skull segmentation	Rib segmentation by model fitting	HU-based threshold segmentation in the Anatomy Visualizer	**Similar** Both subject and predicate device comprise a bone segmentation, but use different well-established techniques
Output Image Type	Curved MIP Ranges	Curved CPR Ranges	Various types, including curved ranges and MIP ranges	**Comparable** For both subject and predicate device, the output image types are commonly used image representations for 3D CT data
Additional Functionality	Picking on 2D view with automatic synchronization of 3D views	Picking on 2D view with automatic synchronization of 3D views	Various functionality for viewing, manipulation, communication, and storage of medical images	**Same** Subject and predicate device both provide picking and synchronization functionality

Features	Subject Device Siemens syngo.CT Skull Unfolding	Predicate Device Siemens syngo.CT Bone Reading	Reference Device Siemens syngo.via VB40	Summary
Measurement Tools	Non-measurement tools (e.g. marker, arrow)	Geometric tools, HU measurement tools, non-measurement tools (e.g. marker, arrow)	Geometric tools, HU measurement tools, non-measurement tools (e.g. marker, arrow)	**Similar** The subject device provides a subset of tools of the predicate device and the reference device.
Editing and Creation Tools	N/A	Tools to create and edit anatomical centerline paths and anatomical labels	Tools to create and edit anatomical centerline paths and anatomical labels	**Different** The subject device provides no editing and creation tools as no labels and centerlines are created.
Intended User	Qualified clinicians	Qualified clinicians	Qualified clinicians	**Same**
Radiological images format	DICOM	DICOM	DICOM	**Same**
Independent of standard of care workflow	Yes; Advanced visualization in addition to standard images	Yes; Advanced visualization in addition to standard images	N/A	**Same**
Modality	Non-contrast CT	Non-contrast CT	Multi-modal, e.g. CT, MR	**Same** Subject and predicate device work on non-contrast CT images
Archiving/Storing	CD-R, film, DVD, USB, Network	CD-R, film, DVD, USB, Network	CD-R, film, DVD, USB, Network	**Same**
Communication	DICOM compatible	DICOM compatible	DICOM compatible	**Same**

IFU Comparison

The subsection provides a comparison discussion of the IFU statement for the subject device and predicate device.

Subject Device Siemens syngo.CT Skull Unfolding	Predicate Device Siemens syngo.CT Bone Reading
syngo.CT Skull Unfolding provides curved MIP images of skull and brain surface for visual assessment by a radiologist.	The syngo.CT Bone Reading is image analysis software for CT volume data sets which has been continuously acquired with computed tomography (CT) imaging systems. The software combines following digital image processing and visualization tools: • multiplanar reconstruction (MPR) thin/thick, maximum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT) • geometric measurement tools (distance line, polyline, marker, arrow, angle) • HU measurement tools (Pixel lens, ROI circle, ROI polygonal, ROI freehand, VOI sphere) • curved MPR visualization (unfolded ribs and spine views), cross-section MPRs

	• tools for creation and editing of anatomical centerline paths • tools for creation and editing of anatomical labels The specific visualizations of spine and rib structures allow for easy manual identification and marking of pathologies such as bone lesions or fractures. Reporting and documentation of results is facilitated by using of appropriate reporting tool, statistics and creation of ranges and snapshots.

The IFU statement of the subject device is not identical as compared to the predicate device, but similar. The predicate device used for this submission is syngo.CT Bone Reading (K123584, clearance date 03/12/2013).

Both devices provide technology to unfold bones. The main difference is that the predicate device is designed for unfolding spine and rib structures and the subject device for the skull.

The subject device represents a visualization method. Despite addressing a different anatomical region, the subject device's IFU can be considered as a subset of the predicate device's IFU. The differences are not critical to the intended use:

- Visualization techniques: Besides showing the unfolded ribs/spine in curved MPR format, the predicate device provides different filtering techniques for visualization of the input CT dataset ("*multiplanar reconstruction (MPR) thin/thick, maximum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT)"*). These possibilities are not unique to the predicate device, but are offered by many standard diagnostic viewing systems (e.g. syngo.via (K191040)). In comparison, the subject device only provides a single visualization technique for the skull and brain surface (curved MIP). However, the user can use a standard diagnostic viewing system to also apply different visualization techniques to the input CT datasets.
- Measurement tools: The predicate device IFU lists geometric and HU measurement tools. Due to the distortions in the subject device, linear measurement tools (e.g. distance line, angle) cannot be used. The subject device enables the use of non-measurement tools (e.g. marker, arrow), but they are not listed within the IFU.
- Tools for creation and editing: The predicate device offers tools to create and edit anatomical centerline paths and anatomical labels. This possibility is specific for the anatomical regions of predicate device (i.e. for spine and ribs) and is not required, and therefore not offered, for the subject device (i.e. skull and brain surface).

Conclusion of the Comparison

To summarize, the IFU differences and differences in the technological characteristics do not affect the subject device's intended use. For the subject device, syngo.CT Skull Unfolding, Siemens used the same testing methods with same workflows as used to clear the predicate device. The development and testing process remain unchanged. Siemens considers syngo.CT Skull Unfolding to be as safe, as effective and with performance substantially equivalent to the commercially available predicate device.

In addition, completion of risk/hazard analysis, non-clinical data-based software validation supports that the used technology in the subject device does not raise different questions of safety and effectiveness.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Non-Clinical Testing

This submission contains performance tests (Non-clinical test reports) to demonstrate continued conformance with special controls for medical devices containing software. Non-clinical tests (integration and functional) were conducted for syngo.CT Skull Unfolding during product development. These tests have been performed to test the ability of the included features of the subject device. The results of these tests demonstrate that the subject device performs as intended. The result of all conducted testing was found acceptable to support the claim of substantial equivalence.

Risk Analysis

The risk analysis was completed, and risk control implemented to mitigate identified hazards. The testing results support that all 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.

Standards and utilized FDA Guidances

Siemens hereby certifies that syngo.CT Skull Unfolding will meet the following voluntary standards covering electrical and mechanical safety listed below, prior to introduction into interstate commerce:

Recognition Number	Product Area	Title of Standard	Date of Recognition	Standards Development Organization
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set; PS 3.1 – 3.20	06/27/2016	NEMA
13-79	Software	Medical Device Software –Software Life Cycle Processes; 62304:2006 (1st Edition)	01/14/2019	AAMI, ANSI, IEC
5-40	Software/ Informatics	Medical devices – Application of risk management to medical devices; 14971 Second Edition 2007-03-01	06/27/2016	ISO
5-114	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices IEC 62366-1:2015	12/23/2016	IEC

For the development of the product as well as the 510(k) submission, the following FDA guidances has been considered:

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]
- Deciding When to Submit a 510(k) for a Software Change to an Existing Device
- Format for Traditional and Abbreviated 510(k)s

VIII. Conclusion

syngo.CT Skull Unfolding has the same intended use and similar indication for use as the predicate device. The result of all testing conducted was found acceptable to support the claim of substantial equivalence. The comparison of technological characteristics, non-clinical performance data, and software validation demonstrates that the subject device is as safe and effective when compared to the predicate device that is currently marketed for the same intended use. For the subject device, syngo.CT Skull Unfolding, Siemens used the same testing with the same workflows as used to clear the predicate device. Siemens considers syngo.CT Skull Unfolding to be as safe, as effective and with performance substantially equivalent to the commercially available predicate device.