K183548
510(K) SUMMARY

SOMATOM CT SCANNER SYSTEMS – SOFTWARE VERSION SOMARIS/5 syngo CT VC50

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355
Date Prepared: February 19, 2019

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.

I. Submitter

Importer/Distributor
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Establishment Registration Number
2240869

Location of Manufacturing Site (1)
Siemens Healthcare GmbH
Siemensstrasse 1
D-91301 Forchheim, Germany
Establishment Registration Number
3004977335

Location of Manufacturing Site (2)
SIEMENS SHANGHAI, MEDICAL EQUIPMENT LTD
278 Zhou Zhu Rd
Shanghai, CHINA, 201318
Establishment Registration Number:
3003202425

Contact Person:
Kim Rendon
Senior Manager Regulatory Affairs
610-448-6480

II. Device Name and Classification

Product Name:	SOMATOM Perspective
Trade Name:	SOMATOM Perspective
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK
Secondary Product Code:	LLZ

Product Name:	SOMATOM Scope/Scope Power
Trade Name:	SOMATOM Scope/Scope Power
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK
Secondary Product Code:	LLZ

Product Name:	SOMATOM Emotion 16
Trade Name:	SOMATOM Emotion 16
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK
Secondary Product Code:	LLZ

III. Predicate Device

Primary Predicate Device:

Trade Name:	SOMATOM Computed Tomography System Family Scanners
510(k) Number:	K142955
Clearance Date:	November 24, 2015
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK
Recall Information:	All applicable recalls are considered and addressed as part of the design control process

Predicate Device:

Trade Name:	SOMATOM Perspective
510(k) Number:	K151765
Clearance Date:	March. 25, 2016
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK
Recall Information:	All applicable recalls are considered and addressed as part of the design control process

Predicate Device:

Trade Name:	SOMATOM Scope/Scope Power
510(k) Number:	K151749
Clearance Date:	March.18, 2016
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK
Recall Information:	All applicable recalls are considered and addressed as part of the design control process

Predicate Device:

Trade Name:	SOMATOM Emotion 6/16
510(k) Number:	K151752
Clearance Date:	November.12, 2015
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK
Recall Information:	All applicable recalls are considered and addressed as part of the design control process

Predicate Device

Trade Name:	SOMATOM Force, SOMATOM Definition Flash, SOMATOM Drive, SOMATOM Definition Edge, SOMATOM Definition AS Open, SOMATOM Definition AS/AS+, SOMATOM Confidence
510(k) Number:	K173630
Clearance Date:	March 30, 2018
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK
Recall Information:	All applicable recalls are considered and addressed as part of the design control process

IV. Device Description

Siemens intends to market a new software version, SOMARIS/5 syngo CT VC50 for the following SOMATOM Computed Tomography (CT) Scanner Systems:

- SOMATOM Perspective
- SOMATOM Scope/Scope Power
- SOMATOM Emotion16

The subject devices SOMATOM CT Scanner Systems with SOMARIS/5 syngo CT VC50 are Computed Tomography X-ray Systems which support continuously rotating tube-detector system and function according to the fan beam principle. The SOMATOM CT Scanner Systems with software version SOMARIS/5 syngo CT VC50 produce CT images in DICOM format, which can be used by trained staff for post-processing applications commercially distributed by Siemens Healthcare and other vendors as an aid in diagnosis, treatment preparation and therapy planning support (including, but not limited to, Brachytherapy, Particle including Proton Therapy, External Beam Radiation Therapy, Surgery). The computer system delivered with the CT scanners is able to run optional post processing applications.

The platform software for the SOMATOM CT Scanner Systems, SOMARIS/5 syngo CT VC50, is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation. The subject devices with software version SOMARIS/5 syngo CT VC50 will support the following modifications in comparison to the predicate devices:

1) **Modified Indications for Use Statement**
2) **Software version SOMARIS/5 syngo CT VC50 (See Table 1.)**
3) **Update 510(k) Information**

Table 1: Overview of SW modifications to CT System Scanners with SOMARIS/5 syngo CT VC50 SW

#	SOMATOM CT System Scanner with SOMARIS/5 syngo CT VC50 property	Subject Devices		
		SOMATOM Perspective	SOMATOM Scope/Scope Power	SOMATOM Emotion16
1	HD FoV 3.0	Modified	Modified	N/A
2	IT Hardening	Enabled	Enabled	Enabled
3	Scan Protocol Management in Teamplay	Unmodified	Unmodified	Enabled
4	Team Viewer	Unmodified	Unmodified	Enabled
5	Dual Topo	Unmodified	Unmodified	Enabled

A comparison of these modifications with respect to the predicate devices is provided in the "**Comparison of Technological Characteristics with the Predicate Device**" section below. Software version SOMARIS/5 syngo CT VC50 will be offered as an optional upgrade for the applicable existing SOMATOM CT Systems.

V. Indications for Use

SOMATOM Perspective

This computed tomography system is intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data.

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

The images delivered by the system can be used by trained staff as an aid in diagnosis and treatment preparation.

However, the images delivered by this system should not be used as an aid in radiation therapy planning.

For cardiac imaging, which is an option on the system, a reconstruction algorithm (iTRIM – Iterative Temporal Resolution Improvement Method) is used. iTRIM improves the temporal resolution of cardiac CT images compared to conventional cardiac CT image reconstruction. Actual results obtained with iTRIM can vary depending on the particular clinical situation.

This CT system can be used for low dose lung cancer screening in high risk populations.*

*As defined by professional medical societies. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

SOMATOM Scope/ Scope Power

This computed tomography system is intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data.

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

The images delivered by the system can be used by trained staff as an aid in diagnosis, treatment preparation and radiation therapy planning.

This CT system can be used for low dose lung cancer screening in high risk populations.*

*As defined by professional medical societies. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

SOMATOM Emotion 16
This computed tomography system is intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data.

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

The images delivered by the system can be used by trained staff as an aid in diagnosis and treatment preparation.

However, the images delivered by this system should not be used as an aid in radiation therapy planning.

This CT system can be used for low dose lung cancer screening in high risk populations.*

*As defined by professional medical societies. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

VI. Comparison of Technological Characteristics with the Predicate Device

The SOMATOM CT Scanner Systems with software version SOMARIS/5 syngo CT VC50 provides the same technological characteristics in terms of materials, energy source, and control mechanisms when compared to the predicate devices. The software of these scanners has been modified or improved in comparison to the predicate devices to support enhanced device functionality.

The device specific software features supported for software version SOMARIS/5 syngo CT VC50 depend on the SOMATOM CT Scanner Systems technological characteristics and are provided as optional features for updating the installed base: SOMATOM Perspective, SOMATOM Scope/Scope Power and SOMATOM Emotion 16 CT systems. A pre-condition for all newly supported subject device software modifications is that the technological characteristics of the hardware must support its intended software usage.

The intended use, fundamental scientific technology, and hardware for the SOMATOM Perspective, SOMATOM Scope/Scope Power and SOMATOM Emotion 16 remains unchanged from the predicate devices.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Scanner Principle- Whole body X-Ray Computed Tomography Scanner
- System Acquisition – Continuously rotating tube detector system
- Iterative Reconstruction – Support of various iterative reconstruction methods
- Workplaces – Support of workplaces that include reconstruction and image evaluation software
- Patient table
- Patient table foot switch for movement

The following technological differences exist between the subject device and predicate devices:

- Software version SOMARIS/5 syngo CT VC50
- Support of additional cybersecurity features

With the introduction of the next generation "HD FoV 3.0," phantom testing showed that the SOMATOM Perspective due to its differing system geometry cannot meet an HU accuracy of +/- 20 HU as with the predicate device K173630. Therefore, the HU accuracy claim was modified to +/- 25 HU for the SOMATOM Perspective platform. This change is noted in the User Instruction documentation.

There are no hardware modifications for the subject devices in comparison to the predicate devices. All previously cleared predicate device hardware properties and components remain unchanged.

Additionally, low dose lung cancer screening was approved for the predicate device in K142955, the subject devices demonstrate substantial equivalence for the indication based on substantially equivalent image quality and dose metrics compared to that predicate.

A tabular summary of the comparable software properties for the subject devices with software version SOMARIS/5 syngo CT VC50 and the predicate devices are listed in **Table 2**.

Table 2: Device Software Comparison for Subject and Predicate Devices

Software Property	***Subject Device***		***Predicate Devices***			
	SOMATOM Perspective	***SOMATOM Emotion 16***	***SOMATOM Perspective***	***SOMATOM Scope/Scope Power***	***SOMATOM Emotion 6/16***	**SOMATOM Force, SOMATOM Definition Flash, SOMATOM Drive, SOMATOM Definition Edge, SOMATOM Definition AS Open, SOMATOM Definition AS/AS+, SOMATOM Confidence**
	SOMATOM Scope/Scope Power					
	syngo CT VC50		***K151765***	***K151749***	***K151752***	***K173630***
Operating System	Windows based SOMARIS/5 syngo CT VC50	Windows based SOMARIS/5 syngo CT VC50	Windows based SOMARIS/5	Windows based SOMARIS/5	Windows based SOMARIS/5	Windows based SOMARIS/7
Software	IT Hardening	IT Hardening	IT features supported that protect against cybersecurity attacks	IT features supported that protect against cybersecurity attacks	IT features supported that protect against cybersecurity attacks	IT Hardening
	Scan protocol management in Teamplay	Scan protocol management in Teamplay	Same as subject device	Same as subject device	N/A	Scan protocol management in Teamplay
	HD FoV 3.0	N/A	HD FoV	HD FoV	N/A	HD FoV 3.0
	Team Viewer	Team Viewer	Same as subject device	Same as subject device	net viewer	N/A
	Dual Topo	Dual Topo	Dual Topo	Dual Topo	N/A	N/A

Any differences in technological characteristics do not raise different questions of safety and effectiveness. Siemens believes that the subject devices are substantially equivalent to the

predicate devices. Testing and validation is completed. Test results show that the subject devices, the SOMATOM CT Scanner Systems with software version SOMARIS/5 syngo CT VC50, are comparable to the predicate devices in terms of technological characteristics and safety and effectiveness and therefore are substantially equivalent to the predicate devices.

VII. Performance Data

Non Clinical Testing

Non-clinical test (integration and functional) including phantom tests were conducted for the SOMATOM CT Scanner Systems during product development. The modifications described in this Premarket Notification were supported with verification and validation testing. Siemens claims conformance to the following performance standards: ISO 14791, NEMA XR-29, IEC 61223-2-6, IEC 61223-3-5, IEC 62304, NEMA XR-25, and DICOM 3.1-3.20.

Electrical Safety and Electromagnetic Compatibility (EMC) testing were conducted on the SOMATOM CT Scanner Systems in accordance with the following standards: IEC 60601-1, 60601-2-44, and 60601-1-2. Completed Forms FDA 3654 are provided within this submission.

Table 3: FDA Guidance Documents

FDA Guidance Document and Effective Date	
1.	Guidance for Industry and FDA Staff – **User Fees and Refunds for Premarket Notification Submissions 510(k) -** Document issued on October 2, 2017
2.	Guidance for Industry and Food and Drug Administration Staff: **Refuse to Accept Policy for 510(k)s -** Document issued on January 30, 2018
3.	Guidance for Industry and FDA Staff: **Format for Traditional and Abbreviated 510(k)s - Guidance for Industry and FDA Staff -** Document issued on August 12, 2005
4.	Guidance for Industry and FDA Staff: **Deciding when to submit a 510(k) for a change to an existing device -** Document issued on October 25, 2017
5.	Guidance for Industry and Food and Drug Administration Staff: **The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] -** Document Issued on July 28, 2014
6.	Guidance for Industry and FDA Staff: **Guidance for the Content of Premarket Submission for Software in Medical Devices -** Document issued on May 11, 2005
7.	Guidance for Industry and FDA Staff: **Guidance for Off-The-Shelf Software Use in Medical Devices -** Document issued on September 9, 1999
8.	Guidance for Industry and FDA Staff: **Applying Human Factors and Usability Engineering to Medical Devices** - Document issued February 3, 2016
9.	Guidance for Industry and FDA Staff: **Pediatric Information for X-ray Imaging Device Premarket Notifications -** Document issued on November 28, 2017
10.	Guidance for Industry and FDA Staff: **Content of Premarket Submissions for Management of Cybersecurity in Medical devices -** Document issued on October 2, 2014
11.	Guidance for Industry and FDA Staff: **Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices -** Document issued on July 11, 2016
12.	Guidance for Industry and Food Drug Administration Staff: **Design considerations and Pre-Market Submission recommendations for Interoperable Medical devices -** Document Issued on September 6, 2017

Verification and Validation

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 performance data demonstrates continued conformance with special controls for medical devices

containing software. The Risk Analysis was completed and risk control implemented to mitigate identified hazards. The testing supports that all software specifications have met the acceptance criteria. Testing for verification and validation supports 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. Cybersecurity information in accordance with guidance document "Content of Premarket Submissions for Management of Cybersecurity Medical Devices issues on October 2, 2014" is included within this submission**.**

Summary

The features described in this premarket notification are supported with verification and validation testing, dosimetry and imaging performance, and analysis of phantom images to assess device and feature performance during product development. The risk analysis was completed and risk control implemented to mitigate identified hazards. The test results show that all of the software specifications have met the acceptance criteria. Verification and validation testing of the device was found acceptable to support the claim of substantial equivalence.

General Safety and Effectiveness Concerns

The device labeling contains instructions for use as well as necessary cautions and warnings to provide for safe and effective use of the device. Risk management is ensured via a system related risk analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing according to the Risk Management process. In order to minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

VIII. Conclusions

The predicate devices were cleared based on the results of non-clinical testing including verification and validation, phantom tests, and supportive literature. The subject device is also tested using the same methods as used for the predicate devices. The non-clinical data supports the safety of the device and the software verification and validation demonstrates that the subject device SOMATOM CT Scanner Systems should perform as intended in the specified use conditions. The data included in this submission demonstrates that the SOMATOM CT Scanner Systems perform comparably to the predicate devices currently marketed for the same intended use. Since both devices were tested using the same methods, Siemens believes that the data generated from the SOMATOM CT Scanner Systems testing supports a finding of substantial equivalence.