Siemens Medical Solutions USA, Inc.
Martin Rajchel
Regulatory Affairs Specialist
40 Liberty Boulevard, Mail Code 65-1A
MALVERN, PA 19355

October 3, 2018

Re: K182050
Trade/Device Name: Linear Accelerator Control Console Software v13.1.010 Update for Siemens PRIMUS™, ONCOR™, ARTISTE™, and *syngo*® RT Therapist & RT Oncologist Workspaces, v4.3.1_MR3
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: July 30, 2018
Received: July 31, 2018

Dear Martin Rajchel:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182050

Device Name

ccNode Software v13.1.010 Update for Siemens PRIMUS™, ONCOR™, ARTISTE™, and syngo® RT Therapist & RT Oncologist Workspaces, v4.3.1_MR3

Indications for Use *(Describe)*

The intended use of the SIEMENS branded ARTISTE™, ONCOR™ and PRIMUS™ family of linear accelerator systems is to deliver X-Ray photon and electron radiation for the therapeutic treatment of cancer.

The linear accelerator systems are high-dose and high-dose rate medical linear accelerators optimized for 3D conformal radiation therapy, intensity-modulated radiation therapy (IMRT), modulated arc therapy (mARC) and precision stereotactic radiation therapy for lesions, tumors and conditions anywhere in the head and body where radiation therapy is indicated.

The Control Console is the operations center for the digital linear accelerator. It contains the digital linear accelerator computer, monitor, and keyboard. From the Control Console, the user can program, initiate, monitor, and control treatments.

The syngo® RT Therapist Workspace is a component of the linear accelerator system and is based on the syngo® architecture. The syngo® RT Therapist workspace contains software applications to support patient selection/setup, patient positioning verification, treatment delivery/verification, and treatment recording.

The syngo® RT Oncologist Workspace is an optional accessory to the linear accelerator system and permits localization, contouring, segmentation, image review and review and approval of treatment plan parameters. In addition, it includes tools and administrative functions to aid in the diagnosis, staging, and prescription of radiation therapy.

The syngo® RT Therapist and the syngo® RT Oncologist Workspaces v4.3.1_MR3, can be interfaced with third party OIS, V&R, TPS, and PACS devices conforming to the DICOM Standard.

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.

510(k) Summary

ccNode Software v13.1.010 Update for Siemens PRIMUS™, ONCOR™, ARTISTE™, and *syngo*® RT Therapist & RT Oncologist Workspaces, v4.3.1_MR3

Company: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355, USA
Establishment Registration Number: 2240869

Date Prepared July 30, 2018

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR § 807.92.

1. General Information

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

Manufacturing Sites:
Siemens AG, Medical Solutions
Radiation Oncology
Doris-Ruppenstein-Str. 4
Erlangen, Germany, 91052
Registration Number: 3006894636

2. Contact Information

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3. Device Name and Classification

Trade name	ccNode Software v13.1.010 Update for Siemens PRIMUS™, ONCOR™, ARTISTE™, and *syngo*® RT Therapist & RT Oncologist Workspaces, v4.3.1_MR3
Classification Name	Medical charged-particle radiation therapy system
Classification Panel:	Radiology
Regulation Number:	21 CFR § 892.5050
Device Class:	II
Product Code:	IYE

4. Legally Marketed Predicate Device

Trade Name	ARTISTE Solution with SYS_VC10C, PHASE 2 Update, with *syngo* RT Therapist & RT Oncologist Workspaces, V4.3.1_MR1
510(k) Number	K142434, Cleared November 21, 2014
Classification Name:	Medical charged-particle radiation therapy system
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.5050
Classification:	Class II
Product Code:	Primary: IYE

5. Device Description

The subject device is a modification of the previously cleared ARTISTE Solution with SYS_VC10C, PHASE 2 Update, with *syngo* RT Therapist & RT Oncologist Workspaces, V4.3.1_MR1 (K142434). The modification consists of an update to the LINAC Control Console Software (v13.1.010) to enhance the safety of the Automatic Movement Protection feature.

Listed below are additional minor software updates:

- *IBL*: enabling pressure & temperature compensation for imaging beams
- *MON 2*: adjustments to the secondary dose monitoring system for small total doses to terminate radiation when the selected number of MUs is exceeded by not more than 10% (valid for <= 250 MU)
- *Treatment Timer*: adjustments to the preset value calculation for the maximum allowed treatment time

There is no new manufacturing of Siemens Medical Linear Accelerators as of October 1, 2012, and therefore no forward production of the subject device. The subject device will only be offered as customer support to the installed base and as optional interface upgrades to support third party Oncology Information Systems (OIS).

6. Indication for Use

The indications for use for the subject device is the same as the predicate device:

The intended use of the SIEMENS branded ARTISTE™, ONCOR™ and PRIMUS™ family of linear accelerator systems is to deliver X-Ray photon and electron radiation for the therapeutic treatment of cancer.

The linear accelerator systems are high-dose and high-dose rate medical linear accelerators optimized for 3D conformal radiation therapy, intensity-modulated radiation therapy (IMRT), modulated arc therapy (mARC) and precision stereotactic radiation therapy for lesions, tumors and conditions anywhere in the head and body where radiation therapy is indicated.

The Control Console is the operations center for the digital linear accelerator. It contains the digital linear accelerator computer, monitor, and keyboard. From the Control Console, the user can program, initiate, monitor, and control treatments.

The syngo® RT Therapist Workspace is a component of the linear accelerator system and is based on the syngo® architecture. The syngo® RT Therapist workspace contains software applications to support patient selection/setup, patient positioning verification, treatment delivery/verification, and treatment recording.

The syngo® RT Oncologist Workspace is an optional accessory to the linear accelerator system and permits localization, contouring, segmentation, image review and review and approval of treatment plan parameters. In addition, it includes tools and administrative functions to aid in the diagnosis, staging, and prescription of radiation therapy.

The syngo® RT Therapist and the syngo® RT Oncologist Workspaces v4.3.1_MR3, can be interfaced with third party OIS, V&R, TPS, and PACS devices conforming to the DICOM Standard.

7. Substantial Equivalence

ccNode Software v13.1.010 Update for Siemens PRIMUS™, ONCOR™, ARTISTE™, and syngo® RT Therapist & RT Oncologist Workspaces, v4.3.1_MR3 is substantially equivalent to the following predicate device:

Predicate Device	FDA Clearance Number	FDA Clearance Date	Product Code
ARTISTE Solution with SYS_VC10C, PHASE 2 Update, with *syngo* RT Therapist & RT Oncologist Workspaces, V4.3.1_MR1	K142434	November 21, 2014	IYE

The comparison of technological characteristics, non-clinical performance data, and software verification and validation data demonstrates that the subject device is as safe and effective when compared to the predicate device currently marketed for the same intended use.

8. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device

The subject device ccNode Software v13.1.010 Update for Siemens PRIMUS™, ONCOR™, ARTISTE™, and syngo® RT Therapist & RT Oncologist Workspaces, v4.3.1_MR3, is substantially equivalent to the predicate device, ARTISTE Solution with SYS_VC10C, PHASE 2 Update, with *syngo* RT Therapist & RT Oncologist Workspaces, V4.3.1_MR1, with regard to the operational environment, programming language, operating system, and performance.

The subject device conforms to the IEC 62304, Edition 1.0, 2006-05, standard for software medical devices and other relevant IEC and NEMA standards.

While the software modifications for the subject device present some differences in technological characteristics compared to the predicate device, these differences have been tested and the conclusions from the non-clinical data suggests that the features bear an equivalent safety and performance profile to that of the predicate device.

9. Nonclinical Performance Testing

The following performance testing was conducted on the subject device:

- Software verification and validation testing was completed in accordance with the FDA guidance document, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*", dated May 11, 2005.

The results from each set of tests demonstrate that the device performs as intended and is thus substantially equivalent to the predicate device to which it has been compared.

ccNode Software v13.1.010 Update for Siemens PRIMUS™, ONCOR™, ARTISTE™, and syngo® RT Therapist & RT Oncologist Workspaces, v4.3.1_MR3 conforms to the following standards for Radiological Oncology devices and their major components:

Title of Standard	Version	Publication Date
IEC 61217:2011 Radiotherapy equipment - Coordinates, movements, and scales	Ed. 2.0	8-Sep-09
IEC 62274:2005-05 Medical electrical equipment - safety of radiotherapy record and verify systems	Ed. 1.0	9-Sep-08
IEC 60976:2007-10: Medical electrical equipment - Medical electron accelerators - Functional performance characteristics	Ed. 2.0	18-Mar-09
ISO 14971:2007: Medical devices - Application of risk management to medical devices	Ed. 2.0	27-Jun-16
IEC 62304:2006: Medical device software – Software life cycle processes	Ed. 1.0	9-May-06

IEC 60601-1:1988 + A1 +A2 /EN 60601-1:1990 + A1:1993 + A2:1995/UL 60601-1:2003: Medical Electrical Equipment, General Requirements for Safety	Ed. 2.0	7-Mar-95
IEC 60601-1-4:2000, Consolidated Ed. 1.1, Medical Electrical Equipment - Part 1-4: General Requirements for Collateral Standard: Programmable Electrical Medical Systems.	Ed. 1.1	7-Apr-00
IEC 60601-2-1:1998 +A 1 2002:Medical electrical equipment - Part 2-1: Particular requirements for the safety of electron accelerators in the range 1 MeV to 50 MeV	Ed. 2.0	30-Jun-98
IEC 62366:2007: Medical Devices - Application of usability engineering to medical devices. & IEC 60601-1-6 Collateral Standard usability	Ed. 1.0	18-Oct-07
IEC 60601-1-1:2000:Medical electrical equipment - Part 1-1:General requirements for safety-Collateral standard: Safety requirements for medical electrical systems. (General).	Ed. 2.0	14-Dec-00
IEC 60601-1-2:2007: Medical electrical equipment - Part 1 - 2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility -Requirements and tests	Ed. 3.0	30-Mar-07

No clinical tests were conducted to support the claim of substantial equivalence between the subject and predicate device.

10. 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 compliance with ISO 14971:2007 to identify and provide mitigation of potential hazards in a risk analysis early in the design phase and continuously throughout the development of the product. These risks are controlled via measures realized in hardware and software development, testing, and product labeling. To minimize risks, Siemens adheres to recognized and established industry practices and standards, such as the IEC 60601-1 series, to minimize electrical and mechanical risk. Furthermore, the device is intended for healthcare professionals familiar with and responsible for using linear accelerator systems to deliver x-ray photon and electron radiation for the therapeutic treatment of cancer.

11. Conclusion as to Substantial Equivalence

While the software modifications for the subject device constitute a difference in technological charcteristics compared to the predicate device, the conclusions from all verification and validation data suggest the features bear an equivalent safety and performance profile as that of the predicate device. The software modifications provide safety enhancements and do not impact the intended use compared to the predicate device.

Siemens concludes that the subject device, ccNode Software v13.1.010 Update for Siemens PRIMUS™, ONCOR™, ARTISTE™, and syngo® RT Therapist & RT Oncologist Workspaces, v4.3.1_MR3, is substantially equivalent to the predicate device, ARTISTE Solution with SYS_VC10C, PHASE 2 Update, with syngo RT Therapist & RT Oncologist Workspaces, V4.3.1_MR1 (K142434)