DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 11, 2016

Siemens Healthcare GmbH
% Mr. Georg Bauer
Responsible Third Party Official
510(k) TPR Deputy Program Manager
TÜV SÜD America, Inc.
1775 old highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K161685
Trade/Device Name: *syngo*®.via protoNeo (Version VA10A)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 14, 2016
Received: June 17, 2016

Dear Mr. Bauer:

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,

For

Robert 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161685

Device Name
syngo®.via protoNeo (Version VA10A)

Indications for Use *(Describe)*
syngo.via protoNeo is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images.

It can be used as a stand-alone device or together with a variety of cleared and unmodified syngo based software options.

syngo.via protoNeo supports interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments.

The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.

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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SIEMENS

510(k) Summary

syngo®.via protoNeo (Version VA10A)

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.

Date prepared: June 1, 2016

1. **Submitter**

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2. **Contact Person**

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3. **Device Name and Classification**

Trade Name:	*syngo*®.via protoNeo (Version VA10A)
Classification Name:	Picture Archiving and Communication System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	LLZ

4. **Legally Marketed Predicate Device**

Trade Name:	*syngo*.via
510(k) Clearance:	K150843
Clearance Date:	April 24, 2015

Classification Name:	Picture Archiving and Communication System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	LLZ
Recall Information:	This predicate device has not been the subject of any design related recalls.

5. Device Description

This premarket submission notification addresses the Siemens *syngo*®.via protoNeo Version VA10A Picture Archiving and Communication System.

syngo®.via protoNeo, version VA10A, is a medical software system that provides tools and features to cover the radiological tasks of reading images. The system receives, stores and distributes images from digital image acquisition devices such as computer tomography and magnetic resonance scanners. The system has workplaces which can be used to review, edit, and manipulate image data, as well as generate quantitative and qualitative data to support an authorized user in diagnosis and treatment planning.

syngo®.via protoNeo version VA10A is a software only medical device. It defines recommended configurations for the hardware to run on. The hardware itself is not seen as a medical device and is not within the scope of this 510(k) submission.

syngo®.via protoNeo is based on a client-server architecture. The server processes and renders the data from the connected modalities. The server provides central services including image processing and temporary storage while incorporating the local database. The client provides the user interface for interactive image viewing and processing and can be installed and stored on each workplace that has a network connection to the server.

Since the majority of the data processing is performed by the server, the client can be installed on standard off-the-shelf computers with a variety of monitor types. The quality of displayed images highly depends on the quality and settings of monitors, graphics cards, and graphics drivers. It is the customer’s responsibility that client monitors are compatible with graphics cards and graphics drivers. It is also the customer's responsibility to use suitable monitors for diagnostic purposes.

In the United States, monitors (displays) should not be used for diagnosis, unless the monitor (display) has specifically received 510(k) clearance for this purpose.

syngo®.via protoNeo and its predicate device have the same fundamental technical characteristics.

6. Intended Use

*syngo.*via protoNeo is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images.

It can be used as a stand-alone device or together with a variety of cleared and unmodified *syngo* based software options.

*syngo.*via protoNeo supports interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments.

The system is not intended for the displaying of digital mammography images for diagnosis in the U.S

7. Summary of Differences Between the Subject Device and the Predicate Device

The differences between the subject device described in this premarket notification and the predicate device are summarized in the following comparison table:

	Subject Device *syngo*.via protoNeo VA10A	**Predicate Device *syngo*.via VB10A**
Manufacturer	Siemens Healthcare GmbH	Siemens AG
Software Architecture	Client-server architecture with enhanced business logic on the client side.	Client-server architecture
Network Bandwidth	Minimum: 3 Mbits/second, 50 ms round-trip	Minimum: 1 Gbit ethernet3
Operating System	Client: Microsoft Windows 7 Server: Microsoft Windows Server 2012 R2	Client: Microsoft Windows 7 SP1 or Microsoft Windows 8.1 Server: Microsoft Windows Server 2008 R2, or Microsoft Windows Server 2012 R2
Patient Browser	Yes, with simplified search functionality and clearer structure of search results	Yes
Ranges	Yes, with a simplified ranges control panel.	Yes
Image Display	CT and MR	DICOM Ultrasound, XA, CT, MR, DX, DR and Nuclear Medicine, including PET.
Imaging Algorithms	- Multiplanar reconstruction (MPR) - Maximum Intensity Projection (MIP) - Volume Rendering Technique	- Multiplanar reconstruction (MPR) - Maximum Intensity Projection (MIP) - Volume Rendering Technique

	(VRT) with edge and surface enhancements and control over rendering parameters - MPR Curved (Curved Planar Reformat, CPR) - Region growing	(VRT) with edge and surface enhancements and control over rendering parameters - MPR Curved - Region growing
Export Data Sets via Network Means	Export to other DICOM nodes.	Export to Windows file system, or other DICOM nodes.

8. Non-Clinical Performance Testing

Non-clinical testing was conducted for the device *syngo*.via protoNeo during product development. The modifications described in this Premarket Notification were supported with verification and validation testing.
Siemens claims conformance to the following standards:

- NEMA PS3 Digital Imaging and Communications in Medicine (DICOM)
- ISO 14971:2007
- ANSI/AAMI ES 60601-1, A1, clauses 14.11 and 14.13
- IEC 62304: 2006
- IEC 62366-1:2015
- IEC 10918-1:1994 + Technical Corrigendum 1:2005
- IEC 15444-1:2005 + Technical Corrigendum 1:2007

Software Verification and Validation

In accordance with the FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005, documentation is included within this submission for software of a Moderate Level of Concern. Non-clinical Testing was conducted during product development. Evidence provided within this submission demonstrates conformance with special controls for medical devices containing software.

Cybersecurity considerations related to *syngo*.via protoNeo are included within this submission. Siemens conforms to cybersecurity requirements by implementing a means to prevent unauthorized access, modification, misuse, denial of use or unauthorized use of information stored, accessed or transferred from a medical device to an external recipient.

A risk analysis, in compliance with ISO 14971:2007, for *syngo*.via protoNeo was conducted and mitigation controls were implemented for identified hazards. Verification and validation testing confirms that all software specifications have been implemented met the defined acceptance criteria. Further, documentation is provided to support the claim of substantial equivalence.

9. Safety and Effectiveness Information

Device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of this device. Risk management was implemented throughout the development process to control potential hazards.

The device does not come into contact with the patient and is only used by trained professionals. The output of the device is evaluated by clinicians, providing for sufficient review to identify and intervene in the event of a malfunction.

Siemens believes that *syngo*.via protoNeo version VA10A is safe and effective as the identified predicate device and does not introduce new safety and effectiveness concerns.

10. Conclusion as to Substantial Equivalence

The comparison of intended use, technological characteristics, performance specifications, device hazards as well as verification and validation results demonstrate that *syngo*.via protoNeo is safe, effective and performs as well as the predicate device.

In summary, Siemens is of the opinion that *syngo*.via protoNeo version VA10A does not introduce any new significant potential safety risks and is substantially equivalent to the predicate device.