DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 14, 2017

Siemens Medical Solution USA, Inc.
% Ms. Patricia Jones
Technical Specialist, Regulatory Submissions
40 Liberty Boulevard 65-1A
MALVERN PA 19355

Re: K163285
Trade/Device Name: syngo Application Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 19, 2017
Received: January 23, 2017

Dear Ms. Jones:

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)*

K163285

Device Name
syngo Application Software

Indications for Use *(Describe)*

The syngo Application Software is a medical software for real-time viewing, image manipulation, 3D-visualization, communication, and storage of medical images and data on exchange media. It is used for diagnostic image viewing and post processing and for viewing and post processing during interventional procedures.

The syngo Application Software can be deployed on independent hardware such as a stand-alone diagnostic review, post-processing, and reporting workstation. It can also be configured within a network to send and receive DICOM data. Furthermore, the syngo Application Software can be deployed on systems of the Siemens Angiography system family. It provides image guided solutions in the operating room, for image guided surgery, by Image Fusion and by navigation systems, image guided solutions in interventional cardiology and electrophysiology and image guided solutions for interventional oncology, interventional radiology, and interventional neuroradiology.

The syngo Application Software can also be combined with fluoroscopy systems or Radiographic systems.

The syngo Application Software can be configured with a variety of syngo or Windows-based software options, which are intended to assist the physician in diagnosis, treatment planning and treatment control. It includes commercially available post-processing techniques and OEM options.

Procedures that can be performed include: minimally invasive surgical procedures and minimally invasive tumor treatment.

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: *syngo* Application Software

**Company:** Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355

**Date Prepared:** January 19, 2017

This 510(k) summary of 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 Systems USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355
**Establishment Registration Number:**
2240869

**Manufacturing Site:**
Siemens Healthcare GmbH
Siemensstr. 1
91301 Forchheim, Germany
**Establishment Registration Number:**
3004977335

**2. Contact Person:**

Ms. Patricia D Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355
Phone: (610) 448-6474
Fax: (610) 640-4481
Email: patricia.d.jones@siemens.com

**3. Device Name and Classification:**

| | |
|---|---|
| **Trade Name:** | *syngo* Application Software |
| **Classification Name:** | Picture Archiving and Communications system |
| **Classification Panel:** | Radiology |
| **Classification Regulation:** | 21 CFR §892. 2050 |
| **Device Class:** | Class II |
| **Product Code:** | LLZ |

**4. Legally Marketed Primary Predicate Device**

| | |
|---|---|
| **Trade Name:** | *syngo* Application Software |
| **510(k) Clearance** | K162541 |
| **Clearance Date** | November 16, 2016 |
| **Classification Name:** | Picture Archiving and Communications 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:**

The *syngo* Application Software is medical diagnostic software for real-time viewing, diagnostic review, post-processing, image manipulation, optimization, communication, reporting and storage of medical images and data on exchange media. It provides image guided solutions in the operating room, for image guided surgery, by Image Fusion and by navigation systems, image guided solutions in interventional cardiology and electrophysiology and image guided solutions for interventional oncology, interventional radiology, and interventional neuroradiology. It can be deployed with a variety of *syngo* or Windows based software options, which are intended to assist the physician in evaluation of digital radiographic examinations, including diagnosis and/or treatment planning.

Siemens *syngo* Application Software is designed to work with digital radiographic, fluoroscopic, interventional and angiographic systems. The software platform with common software architecture, *syngo* application packages and basic services is the same as used with the *syngo* Application Software cleared in K162541.

Siemens Medical Solutions USA, Inc. hereby submits this Traditional 510(k) to request clearance for new software features to the *syngo* Application Software.

**Proposed Device Modifications:**

1. Enhanced *syngo* Embolization Guidance
2. Proposed new product claims associated with device.

The “syngo Application Software” may be installed either on Siemens released PC hardware, on Siemens X-ray systems or on Siemens Angiography Systems. The combination of syngo Application Software and the Siemens released PC Hardware will be marketed as components of the syngo X Workplace.

The *syngo* Application Software is within the same classification regulation and the intended use and the general Indications for Use Statement for Siemens’ Picture Archiving and Communications System.

Proposed new product claims associated with syngo Embolization Guidance:

| Claim # | Labeling Claim |
|---|---|
| 1. | syngo Embolization Guidance automatically detects a catheter that is positioned in a hepatic artery. |
| 2. | syngo Embolization Guidance automatically computes a vessel tree starting at a distinct catheter position and comprising vessel branches that feed a user defined lesion. |
| 3. | syngo Embolization Guidance visualizes the vessels in different colors. The more proximal vessel has a predefined color. Advancing distal in the computed vessel tree, the vessel branches leaving the first bifurcation have other predefined colors. |
| 4. | syngo Embolization Guidance allows the user to define and mark a lesion by means of a sphere. The sphere is created by simply drawing a line in a planar image (MPR or MIP) by which the position and diameter of the sphere is defined – a safety margin can be configured. |
| 5. | syngo Embolization Guidance allows the user to add or remove vessels from the automatically computed vessel tree by selecting the respective vessel branch in a MPR or thin MIP visualization of a 3D dataset. |
| 6. | syngo Embolization Guidance allows to mark lesions and automatically compute the tree of feeding vessels based on contrast-enhanced Cone-beam CT (e.g. syngo DynaCT) and MDCT datasets. |
| 7. | To mark a lesion in the liver syngo Embolization Guidance needs just one user input. |
| 8. | syngo Embolization Guidance can be easily operated from table-side. There is no need to break scrubs and leave the interventional room. |
| 9. | The 3D planning data from syngo Embolization Guidance can help the physician to manually define the radiation free projection for device navigation and hence has the potential to reduce the overall radiation dose* of the intervention".<br><br>* this is individual customer experience - results may vary |

## 6. Indications for Use:

The *syngo* Application Software is a medical software for real-time viewing, image manipulation, 3D-visualization, communication, and storage of medical images and data on exchange media. It is used for diagnostic image viewing and post processing and for viewing and post processing during interventional procedures.

The *syngo* Application Software can be deployed on independent hardware such as a stand-alone diagnostic review, post-processing, and reporting workstation. It can also be configured within a network to send and receive DICOM data. Furthermore, the *syngo* Application Software can be deployed on systems of the Siemens Angiography system family. It provides image guided solutions in the operating room, for image guided surgery, by Image Fusion and by navigation systems, image guided solutions in interventional cardiology and electrophysiology and image guided solutions for interventional oncology, interventional radiology, and interventional neuroradiology.

The *syngo* Application Software can also be combined with fluoroscopy systems or Radiographic systems.

The *syngo* Application Software can be configured with a variety of *syngo* or Windows-based software options, which are intended to assist the physician in diagnosis, treatment planning and treatment control. It includes commercially available post-processing techniques and OEM options.

Procedures that can be performed include: minimally invasive surgical procedures and minimally invasive tumor treatment.

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

The subject device is comparable to general Indications for Use for medical workstation for real-time viewing, image manipulation, 3D-visualization, communication, and storage of medical images and data on exchange media. The subject device has the same intended use, functionality, technology and is considered substantially equivalent to the commercially available Siemens' *syngo* Application Software.

All Software components of the subject device are the same as the one from the predicate device except of the new software improvements to *syngo* Embolization Guidance. The table below provides comparison of the Subject Device modification to the Predicate Device.

| Property | Subject Device: *syngo* Application Software | Predicate Device: *syngo* Application Software (K1625416) | Comparison Results |
|---|---|---|---|
| SW VD20 / New Software-Applications | Enhanced syngo EmbolizationGuidance Automatic feeder detection for lesions inside the liver | syngo EmbolizationGuidance basic functionality | Enhanced automated feature does not raise any new issues of safety or effectiveness. Validation and testing was conducted. |

The Subject Device modifications do not alter its fundamental scientific technology from the 510(k) cleared predicate device Siemens' *syngo* Application Software.

**8. Nonclinical Performance Testing:**

Non-clinical tests were conducted for the *syngo* Application Software during product development.

Siemens claims conformance to the following performance standards:

- 14971
- 60601-1-6
- 62304
- 62366-1
- 80001-1

The modifications described in this Premarket Notification were supported with verification and validation testing.

**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. Non-clinical tests were conducted on the *syngo* Application Software during product development.

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

The Human Factor Usability Validation showed no safety relevant functions that need to be validated with a summative usability validation according to the IEC and FDA Guidelines. The *syngo* Application Software has been found to be safe and effective for intended users, uses and use environments through the design control verification and validation process. No further risk mitigations are necessary.

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. Provided in this submission is a cybersecurity statement that considers IEC 80001-1:2010. The responsibility for compliance with IEC 80001-1-2010 is the hospital. Provided in the Software Section, is the required cybersecurity information.

**Summary of the performance testing data:**
Performance tests were conducted to test the functionality of the *syngo* Application Software. These tests have been performed to assess the functionality of the Subject Device. Results of all conducted testing and clinical assessment were found acceptable and do not raise any new issues of safety or effectiveness. Performance to syngo Embolization Guidance is provided below.

All software validation data 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.

**Performance to syngo Embolization Guidance:**
The syngo Embolization Guidance algorithm has been statistically evaluated using 22 DynaCT test data sets. The automatic detection rate is 73% with a statistical significance of 0.072. The detection rate for an automatic detection including manual correction is 86% with a statistical significance of 0.002. The rate of the missed vessels (false negative) is 23.8%. All results were clinically accepted by a board certified radiologist.

**9. General Safety and Effectiveness Concerns:**
Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing. Furthermore the operators are health care professionals familiar with and responsible for the evaluating and post processing of medical images.

**10. Conclusion as to Substantial Equivalence:**
The predicate device was cleared based on non-clinical supportive information and clinical images and data. Similar non-clinical test results demonstrate that *syngo* Application Software acceptance criteria are adequate for the intended use of the device. The comparison of technological characteristic, non-clinical performance data, clinical images, and software validation data 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.