Dear Ms. Mangum:

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.
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](http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm) for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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/](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/)) and CDRH Learn ([http://www.fda.gov/Training/CDRHLearn](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](http://www.fda.gov/DICE)) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K173637

Device Name

syngo.CT Coronary Analysis

Indications for Use (Describe)

syngo.CT Coronary Analysis is an image analysis software package for evaluating cardiac CT angiography (CTA) volume data sets. Combining 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), curved planar reformation (CPR)), evaluation tools (coronary vessel centerline calculation, stenosis calculation and plaque analysis) and reporting tools (lesion location, lesion characteristics and key images), the software package is designed to support the physician in confirming the presence or absence of physician-identified coronary lesions and evaluation, documentation and follow-up of any such lesion. These visualization/evaluation tools allow for characterization (geometry (length, lumen diameter, cross section area, stenosis grade) and appearance (HU values)) of coronary lesions and lesion size over time, helping the physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue.
Indications for Use

510(k) Number (if known)
K173637

Device Name

syngo.CT Vascular Analysis

Indications for Use (Describe)

syngo.CT Vascular Analysis is an image analysis software package for evaluating enhanced CT images. Combining 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), curved planar reformation (CPR), processing tools (bone removal (based both on single energy and Dual Energy), table removal) and evaluation tools (vessel centerline calculation, lumen calculation, stenosis calculation) and reporting tools (lesion location, lesion characteristics and key images), the software package is designed to support the physician in confirming the presence or absence of physician-identified lesions in blood vessels and evaluation, documentation and follow-up of any such lesion. These visualization/processing/evaluation tools allow for characterization (geometry (length, lumen diameter, cross section area, stenosis grade) and appearance (HU values)) of vascular lesions and lesion size over time, helping the physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue.
510(k) SUMMARY
FOR
SYNGO.CT CORONARY ANALYSIS
AND
SYNGO.CT VASCULAR ANALYSIS

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Date Prepared: March 29, 2018

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

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

Contact Person
Kimberly Mangum
Regulatory Affairs Specialist
Siemens Medical Solutions, Inc. USA
40 Liberty Boulevard
Malvern, PA 19355
Phone: (610) 448 - 6477
Fax: (610) 640 - 4481
Email: kimberly.mangum@siemens-healthineers.com

II. Device Name and Classification
Product Name: syngo.CT Coronary Analysis
Proprietary Name: syngo.CT Coronary Analysis
Classification Name: Computed Tomography X-ray System
Classification Panel: Radiology
CFR Section: 21 CFR §892.1750
Device Class: Class II
Product Code: JAK

Product Name: syngo.CT Vascular Analysis
Proprietary Name: syngo.CT Vascular Analysis
Classification Name: Computed Tomography X-ray System
Classification Panel: Radiology
CFR Section: 21 CFR §892.1750
Device Class: Class II
Product Code: JAK

III. Predicate Device
Predicate Device for syngo.CT Coronary Analysis:
Trade Name: syngo.CT Coronary Analysis
510(k) Number: K100637
IV. Device Description

**syngo.CT Coronary Analysis**

syngo.CT Coronary Analysis is an image analysis post-processing software application designed to support evaluation of the vessels of the heart. This submission describes the following modifications that were made to predicate device syngo.CT Coronary Analysis (K100637, clearance date 5/26/2010):

1) Support of software version SOMARIS/8 VB30 which supports the following functionality:
   a. Coronary Tracing Quality Improvement
   b. Rapid Results Technology Support for Curved Vessel Ranges

2) Update 510(k) Information

Combining digital image processing and visualization tools (multiplanar reconstruction (MPR) thin/thick, minimum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT), curved planar reformation (CPR)), evaluation tools (coronary vessel centerline calculation, stencils calculation and plaque analysis) and reporting tools (lesion location, lesion characteristics and key images), the software package is designed to support the physician in confirming the presence or absence of physician-identified coronary lesions and evaluation, documentation and follow-up of any such lesion. These visualization/evaluation tools allow for characterization of coronary lesions and lesion size over time, helping the physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue.

**syngo.CT Vascular Analysis**

syngo.CT Vascular Analysis is a post-processing software application to support evaluation of the large vessels of the body. This submission describes the following modifications that were made to predicate device syngo.CT Vascular Analysis (K112020, clearance date 08/18/2011):

1) Modified Indications for Use Statement

2) Support of software version SOMARIS/8 VB30 which supports the following functionality:
   a. Rapid Results Technology Support for curved vessel ranges
   b. Bone Removal Quality Improvement
   c. Vessel Tracing Quality Improvement

3) Update 510(k) Information

Combining 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), curved planar reformation (CPR), processing tools (bone removal (based both on single energy and Dual Energy), table removal) and evaluation tools (vessel centerline calculation, lumen calculation, stenosis calculation) and reporting tools (lesion location, lesion characteristics and key images), the software package is designed to support
the physician in confirming the presence or absence of physician-identified lesions in blood vessels and evaluation, documentation and follow-up of any such lesion. These visualization/processing/evaluation tools allow for characterization of vascular lesions and lesion size over time, helping the physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue.

V. Indications for Use

Indications for Use for syngo.CT Coronary Analysis

syngo.CT Coronary Analysis is an image analysis software package for evaluating cardiac CT angiography (CTA) volume data sets. Combining 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), curved planar reformation (CPR)), evaluation tools (coronary vessel centerline calculation, stenosis calculation and plaque analysis) and reporting tools (lesion location, lesion characteristics and key images), the software package is designed to support the physician in confirming the presence or absence of physician-identified coronary lesions and evaluation, documentation and follow-up of any such lesion. These visualization/evaluation tools allow for characterization (geometry (length, lumen diameter, cross section area, stenosis grade) and appearance (HU values)) of coronary lesions and lesion size over time, helping the physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue.

Indications for Use for syngo.CT Vascular Analysis

syngo.CT Vascular Analysis is an image analysis software package for evaluating enhanced CT images. Combining 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), curved planar reformation (CPR), processing tools (bone removal (based both on single energy and Dual Energy), table removal) and evaluation tools (vessel centerline calculation, lumen calculation, stenosis calculation) and reporting tools (lesion location, lesion characteristics and key images), the software package is designed to support the physician in confirming the presence or absence of physician-identified lesions in blood vessels and evaluation, documentation and follow-up of any such lesion. These visualization/processing/evaluation tools allow for characterization (geometry (length, lumen diameter, cross section area, stenosis grade) and appearance (HU values)) of vascular lesions and lesion size over time, helping the physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue.

VI. Comparison of Technological Characteristics with the Predicate Device

At a very high-level overview, the subject and predicate devices are based on the following same/modified technological characteristics.

- Software operating platform SOMARIS8/8
- Support of basic reading Functionality
- 2D/3D vessel visualization tools
- Automated segmentation and removal of obstructive bones and/or vessels
- Support of automated pre-processing and layouts
- Measurement tools that support quantitative assessment and documentation

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

- Software version SOMARIS/8 VB30
- Support of Rapid Results Technology feature
- Improved bone removal functionality
- Improved vessel tracing functionality
A tabular summary of the subject and predicate device technological differences is provided as Table 1 and Table 2 below:

**Table 1: syngo.CT Coronary Analysis Predicate and Subject Device Technological Characteristics Comparison**

<table>
<thead>
<tr>
<th>Property</th>
<th>Subject Device syngo.CT Coronary Analysis</th>
<th>Predicate Device syngo.CT Coronary Analysis (K100637)</th>
<th>Comparison Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software Operating Platform</td>
<td>SOMARIS/8 VB30</td>
<td>SOMARIS/8 VA10</td>
<td>Modified</td>
</tr>
<tr>
<td>Visualization and Segmentation Tools</td>
<td>Basic Visualization and Navigation Tools</td>
<td>Basic Visualization and Navigation Tools</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>Automatic Organ Segmentation</td>
<td>Automatic Organ Segmentation</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>Automatic Vessel Tracing</td>
<td>Automatic Vessel Tracing</td>
<td>Modified</td>
</tr>
<tr>
<td></td>
<td>3D Vessel Visualization Tools</td>
<td>3D Vessel Visualization Tools</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>2D Vessel Visualization Tools</td>
<td>2D Vessel Visualization Tools</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>Vessel Navigation Tools</td>
<td>Vessel Navigation Tools</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>Vessel Definition Tools</td>
<td>Vessel Definition Tools</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>Vessel Evaluation Tools</td>
<td>Vessel Evaluation Tools</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>Result Image Creation</td>
<td>Result Image Creation</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>Integrated Reporting</td>
<td>Integrated Reporting</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>Workflow Automation Support</td>
<td>Workflow Automation Support</td>
<td>Modified</td>
</tr>
<tr>
<td>Archiving and Reporting</td>
<td>User Interface</td>
<td>User Interface</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>Archiving/Storing</td>
<td>Archiving/Storing</td>
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</tr>
<tr>
<td></td>
<td>Communication</td>
<td>Communication</td>
<td>Same</td>
</tr>
</tbody>
</table>

**Table 2: syngo.CT Vascular Analysis Predicate and Subject Device Technological Characteristics Comparison**

<table>
<thead>
<tr>
<th>Property</th>
<th>Subject Device syngo.CT Coronary Analysis</th>
<th>Predicate Device syngo.CT Vascular Analysis (K112020)</th>
<th>Comparison Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software Operating Platform</td>
<td>SOMARIS/8 VB30</td>
<td>SOMARIS/8 VA10</td>
<td>Modified</td>
</tr>
<tr>
<td>Visualization and Segmentation Tools</td>
<td>Basic Visualization and Navigation Tools</td>
<td>Basic Visualization and Navigation Tools</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>Automatic Organ Segmentation</td>
<td>Automatic Organ Segmentation</td>
<td>Modified</td>
</tr>
<tr>
<td></td>
<td>Automatic Vessel Tracing</td>
<td>Automatic Vessel Tracing</td>
<td>Modified</td>
</tr>
<tr>
<td></td>
<td>3D Vessel Visualization Tools</td>
<td>3D Vessel Visualization Tools</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>2D Vessel Visualization Tools</td>
<td>2D Vessel Visualization Tools</td>
<td>Same</td>
</tr>
<tr>
<td>Property</td>
<td>Subject Device syngo.CT Coronary Analysis</td>
<td>Predicate Device syngo.CT Vascular Analysis (K112020)</td>
<td>Comparison Results</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------------------------------------------</td>
<td>------------------------------------------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>Visualization and Segmentation Tools</td>
<td>Vessel Navigation Tools</td>
<td>Vessel Navigation Tools</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>Vessel Definition Tools</td>
<td>Vessel Definition Tools</td>
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<td>Result Image Creation</td>
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<td></td>
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<td>Integrated Reporting</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>Workflow Automation Support</td>
<td>Workflow Automation Support</td>
<td>Modified</td>
</tr>
<tr>
<td>Archiving and Reporting</td>
<td>User Interface</td>
<td>User Interface</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>Archiving/Storing</td>
<td>Archiving/Storing</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>Communication</td>
<td>Communication</td>
<td>Same</td>
</tr>
</tbody>
</table>

The subject device modifications do not alter the fundamental scientific technology of the 510(k) cleared predicate devices syngo.CT Coronary Analysis and syngo.CT Vascular Analysis. The software version has been modified to support improved clinical workflows.

VII. Performance Data
Non-Clinical Testing Summary
Non-clinical tests (integration and functional) were conducted for syngo.CT Coronary Analysis and syngo.CT Vascular Analysis during product development. Performance tests were conducted to test the functionality of syngo.CT Coronary Analysis and syngo.CT Vascular Analysis. The modifications described in this Premarket Notification were supported with verification/validation testing. 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. Siemens claims conformance to the following performance standards:

<table>
<thead>
<tr>
<th>Product Area</th>
<th>Title of Standard</th>
<th>Publication Date</th>
<th>Standards Development Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiology</td>
<td>Digital Imaging and Communications in Medicine (DICOM) Set; PS 3.1 – 3.20</td>
<td>06/27/2016</td>
<td>NEMA</td>
</tr>
<tr>
<td>Software/Informatics</td>
<td>Medical devices – Application of risk management to medical devices; 14971 Second Edition 2007-03-01</td>
<td>08/20/2012</td>
<td>ISO</td>
</tr>
</tbody>
</table>
Non-Clinical Performance (Bench) Testing
Additional non-clinical quantitative performance testing was conducted to demonstrate the functionality and applicability of the subject devices modified features. To demonstrate the coronary tracing quality improvement for subject device syngo.CT Coronary Analysis, quantitative performance testing was conducted to test the following functions:
- Centeredness of the Centerlines
- Tracing of branches
- Coverage of Centerlines

As part of this testing, a sampling of centerlines from a predetermined number of datasets were evaluated. To test for accuracy of centeredness, the derived centerlines were assessed in comparison to the predicate device to demonstrate an improvement in the ability of the subject device application to more accurately follow the vessels in the lumen. Testing for the tracing of branches and coverage of centerlines was conducted on branches that were considered both clinically relevant and clinically irrelevant to assess sensitivity and specificity of branch tracing and coverage. The results of this test demonstrated an increased sensitivity and specificity and improved vessel coverage for the subject device tracing feature in comparison to the predicate device.

To demonstrate the functionality of the vessel tracing quality improvement for subject device syngo.CT Vascular Analysis, the detection rate of a predetermined set of vessels was evaluated to determine whether a vessel was successfully traced if a vessel was expected based on activation of the algorithm. The result of this test demonstrated that the subject device had a higher level of traced vessels in comparison to the predicate device, which supports an improvement of vessel tracing quality in comparison to the predicate device.

Software 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 support the claim of substantial equivalence.

Siemens Healthcare 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
This subject devices provide tools designed for the evaluation of CT images. The fundamental software technology which is provided within the scope of the subject devices is already cleared and remains unchanged in comparison to the predicate devices. The Indications for Use for the subject devices have been adapted to provide a more specific description of the subject device functionality, but does not represent a new intended use. The modifications described in this Premarket Notification were supported with non-clinical performance testing as well as verification and validation testing. The Risk analysis was completed and risk control implemented to mitigate identified hazards.

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 a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing. syngo.CT Coronary Analysis and syngo.CT Vascular Analysis is designed to fulfill the requirements of the applicable safety and performance standards as listed above.
VIII. Conclusions

The subject devices have the same intended use as the predicate devices. The technological characteristics such as image visualization, operating platform, and image manipulation remain unchanged from the predicate device. The predicate devices were cleared based on non-clinical testing including verification and validation testing. The results of these tests demonstrate that the predicate devices are adequate for the intended use. The subject devices are also tested using the same methods and workflows as used for the predicate devices. The comparison of technological characteristics, non-clinical performance data, and software validation included in this submission demonstrates that the subject device is as safe and effective when compared to the predicate devices that are currently marketed for the same intended use. Since both devices were tested using the same methods, Siemens believes that the data generated from the subject devices syngo.CT Coronary Analysis and syngo.CT Vascular Analysis testing supports a finding of substantial equivalence.