NOV 18 2011 K113029

510(k) Summary

as required by 21 CFR Part 807.87(h)

Identification of the Submitter

Submitter:	M. Alaine Medio, RAC PET and PCS Regulatory Projects Manager Siemens Medical Solutions USA, Inc. Molecular Imaging 810 Innovation Drive Knoxville, TN 37932
Telephone Number:	(865)218-2703
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Name / Address of Manufacturer	Siemens Medical Solutions USA, Inc Molecular Imaging 2501 N. Barrington Road Hoffman Estates, IL 60192 USA

Date of Submission:	October 10, 2011

Identification of the product

Device Proprietary Name:	*syngo*.via MI Workflows
Common Name:	Image Processing Software
Classification Name:	Picture Archiving and Communication System per 21 CFR 892.2050
Product Code:	LLZ
Classification Panel:	Radiology
Device Class:	Class II

Marketed Devices to which Equivalence is claimed

Device	Manufacturer	510(k) Number
syngo.via (*syngo*.x)	Siemens Medical Solutions USA, Inc	K092519 (August 27, 2009)
syngo.via MI Workflows (*syngo*.via PET&CT Oncology)	Siemens Medical Solutions USA, Inc	K093621 (February 23, 2010)

Device Description:

The *syngo*.via MI Workflows are software only medical devices which will be delivered on CD-ROM / DVD to be installed onto the commercially available Siemens *syngo*.via software platform by trained service personnel.

syngo.via MI Workflows are medical diagnostic applications for viewing, manipulation, 3D-visualization and comparison of medical images from multiple imaging modalities and/or multiple time-points. The application supports functional data, such as PET or SPECT as well as anatomical datasets, such as CT or MR. The images can be viewed in a number of output formats including MIP and volume rendering.

syngo.via MI Workflows enable visualization of information that would otherwise have to be visually compared disjointedly. *syngo*.via MI Workflows provide analytical tools to help the user assess, and document changes in morphological or functional activity at diagnostic and therapy follow-up examinations.

syngo.via MI workflows support the interpretation and evaluation of examinations and follow up documentation of findings within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments.

The *syngo*.via MI Workflows are based on the syngo.PET&CT Oncology package (K093621and are merely adding the ability to launch additional commercially available software such as Siemens Scenium product (K061545) on the *syngo*.via platform.

syngo.via MI Workflows are intended to be run on the Siemens *syngo*.via software platform (K092519) either alone or with other advanced commercially cleared applications.

Safety and Effectiveness:

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 risk analyses in compliance with ISO 14971:2007 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. Siemens Medical Solutions, USA Inc. adheres to recognized and established industry standards for development.

Indications for Use:

syngo.via MI Workflows are medical diagnostic applications for viewing, manipulation, 3D-visualization and comparison of medical images from multiple imaging modalities and/or multiple time-points. The application supports functional data, such as PET or SPECT as well as anatomical datasets, such as CT or MR.

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Note: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of the separate unregistered images. *syngo*.via MI Workflows are a complement to these standard procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Alaine Medio, RAC
PET and PCS Regulatory Projects Manager
Siemens Medical Solutions USA Inc.
Molecular Imaging
810 Innovation Drive
KNOXVILLE TN 37932

NOV 18 2011

Re: K113029
Trade/Device Name: Syngo.via MI Taskflows
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 10, 2011
Received: October 20, 2011

Dear Ms. Medio:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number ~~(if known)~~: K113029

Device Name: *syngo*.via MI Taskflows

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Prescription Use___X___ (Part 21 CFR 801 Subpart D) OR Over the Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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