K101666

AUG 10 2010

510(k) Summary

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.

- GENERAL INFORMATION

~~FDA CDRH DMC~~

~~JUN 14 2010~~

~~Received~~

Establishment:

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• Registration Number:	3002808157
• Contact Person:	Sabine Schroedel Regulatory Affairs Manager Telephone: +49 (9131) 84-8285 Telefax: +49 (9131) 84-2792

Device Name and Classification:

• Trade Name:	*syngo*.plazaVA20A
	Classification Name: Picture Archiving and Communications System
• Classification Panel:	Radiology
• CFR Section:	21 CFR §892.2050
• Device Class:	Class II
• Product Code:	LLZ

Date of Submission:

May 17, 2010

- SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

• **Device Description and Intended Use:**

syngo.plaza is a Picture Archiving and Communication System intended to display, process, read, report, communicate, distribute, store, and archive digital medical images, including mammographic images.
It supports the physician in diagnosis and treatment planning.

For primary image diagnosis in Mammography only uncompressed or non-lossy compressed images and only preprocessed DICOM "For Presentation" images must be

used. Also monitors (displays) and printers which received FDA clearance for Mammography must be used.
syngo.plaza also supports DICOM Structured Reports.

In a comprehensive imaging suite, *syngo*.plaza integrates Hospital / Radiology Information Systems (HIS/RIS) to enable customer specific workflows.
syngo.plaza optionally uses a variety of advanced postprocessing applications.

Note:
Web-based image distribution is not intended for reporting.

syngo.plaza Workplaces

The three *syngo*.plaza workplace deployments ...

a) *syngo*.plaza Cluster Client

b) *syngo*.plaza Web Client

c) *syngo*.plaza Standalone Workstation

... are medical diagnostic and viewing workstations intended for post processing, reading, reporting, viewing and communicating / distributing of radiological softcopy images and so allow radiologists and radiological technicians to receive and process all data needed.

By usage of only specific FDA approved monitors validated together with the software, diagnosis on digital mammography images is possible.

Integration
The integration of *syngo*.plaza shall be applied at different levels and by using technologies like sharing the same HW/SW platform, offering an open interface for other vendors to connect with other DICOM nodes and especially the DICOM Archive functionality, with other information systems (mainly RIS).

- **Technological Characteristics:**

syngo.plaza is a "software only"-system, which will be delivered on CD-ROM / DVD to be installed on common IT hardware. *syngo*.plaza will be installed by Siemens service engineers.

The backend communication and storage solution is based in Windows 2008 operating systems as described in the predicate devices *syngo*.plaza VA10A (093612) and *syngo*.x (K092519). The clients are based on Windows XP as also described in the predicate devices *syngo*.plaza VA10A (093612) and *syngo*.x (K092519)

The *syngo*.plaza will be marketed as a software only solution for the end-user (with recommended hardware requirements). It will be installed by trained service engineers only. Any special needs such as integration in a specific environment and updates / upgrades will be covered by individual service contract and fulfilled by special trained service technicians. This is also applicable for the predicate devices *syngo*.plaza VA10A (093612) and *syngo*.x (K092519).

The herewith described *syngo*.plaza VA20A supports DICOM formatted images and objects which is also described for the predicate devices *syngo*.plaza VA10A (093612), *syngo*.x (K092519) and *syngo* Imaging (K071114).

- **Summary of Non-Clinical Testing:**

The software verification and validation (Unit Test Level, Integration Test Level and System Test Level) was performed for all newly developed components and the complete system according the following standards:

- DICOM Standard [2008]
- JPEG/JPEG 2000 Standard [1992, 2002]
- SMPTE Test Pattern [1995]
- ISO 14971:2007
- IEC 60601-1-4 + A1 [1999]
- IEC 60601-1-6 [2006]
- HL7 [2006]
- IEC 62304 [2006]
- ISO/IEC 13818 [2009]

After completion of the system test and comparison of the test results with the software release acceptance criteria, Siemens is of the opinion, that *syngo*.plaza is substantially equivalent to and performs as well as the predicate device.

- **General Safety and Effectiveness Concerns:**

The device labelling contains instructions for use and any necessary cautions and warning, to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing.

- **Substantial Equivalence:**

The *syngo*.plaza, addressed in this premarket notification, is substantially equivalent to the following commercially available devices:

Siemens	*syngo*.plaza VA10A	K093612
Siemens	*syngo* Imaging V30	K071114
Siemens	*syngo*.X	K092519

The *syngo*.plaza described in this 510(k) has the same intended use and similar technical characteristics as the devices listed above in regard to the specific functionalities.
In summary, Siemens is of the opinion that *syngo*.plaza VA20A does not introduce any new
potential safety risks and is substantially equivalent to and performs as well as the predicate devices.

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

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AUG 1 0 2010

Re: K101666
Trade/Device Name: *syngo*, plaza VA20A
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 16, 2010
Received: July 22, 2010

Dear Mr. Preiss:

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,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

AUG 1 0 2010

INDICATIONS FOR USE

510(k) Number (if known):_____
Device Name: *syngo*.plaza VA20A

Indications For Use:

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Note:
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Prescription Use _X_ AND / OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of In Vitro Diagnostics (OIVD)

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

510K K101666