K133259
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510(k) Summary: Ysio Max

Company: Siemens Medical Systems, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

JAN 2 4 2014

Date Prepared: November 20, 2013

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 Solutions, Inc.
51 Valley Stream Parkway
Malvern, PA 19355
Establishment Registration Number:
2240869
Manufacturing Site:
SIEMENS AG Sector Healthcare
Röntgenstrasse 19 – 21
D-95478 Kemnath, Germany
Establishment Registration Number:
3002466018

2. Contact Person:

Mr. Darren Dorman
Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
51 Valley Stream Pkwy • Mail Code D02
Malvern, PA 19355, USA
Phone: +1 610 219-9066 • Fax: +1 610 448-1787
Email: darren.dorman@siemens.com

3. Device Name and Classification:

Trade Name:	Ysio Max
Classification Name:	Stationary X-Ray system
Regulation:	Radiology
Review Panel:	Radiology
Device Code:	KPR
Regulation Number:	892.1680
Device Class:	Class II

4. Legally marketed Predicate device:

Trade Name:	Ysio
Classification Name:	Stationary X-Ray system
Regulation:	Radiology
Review Panel:	Radiology
Product Code	KPR
Regulation Number:	892.1680
Device Class:	Class II

5. Device Description:

The Ysio Max Radiography X-ray system is designed as a modular system with components such as ceiling suspension with X-ray tube, Bucky wall stand, Bucky table, X-ray generator, portable wireless and fixed integrated detectors, that may be combined into different configurations to meet specific customer needs.

The Ysio Max components may be used together with fluoroscopy tables (i.e. Luminos Agile or Luminos dRF) to facilitate radiographic examinations on such tables, when not needed for fluoroscopy.

The Ysio Max Radiography X-ray system is based on the currently available predicate Ysio.

6. Indication for Use:

The Ysio Max is a radiographic system used in hospitals, clinics, and medical practices. Ysio Max enables radiographic and tomographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. It can also be used for intravenous, small interventions (like biopsy, punctures, etc.) and emergency (trauma, critical ill) applications. Exposures may be taken with the patient sitting, standing, or in the prone position. The Ysio Max system is not meant for mammography.

The Ysio Max uses integrated or portable digital detectors for generating diagnostic images by converting x-rays into electronic signals. Ysio Max is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.

7. Substantial Equivalence:

The **Ysio Max** is substantially equivalent to the predicate Ysio:

510(k) Number	Date of Clearance	Device Name	Comparable Properties
K081722	08/22/2008	Ysio	- Indication for use - X-ray technology - Image processing - Mechanical design

Some of the components used on the Ysio Max i.e. X-Ray generator, X-Ray tube, user interface, and displays are being used in the predicate Ysio.

8. Summary of Technological Characteristics of the Subject Device as compared with the Predicate Device:

The **Ysio Max** Radiography X-ray system is designed as a modular system of X-Ray components (ceiling suspension with X-Ray tube, Bucky wall stand, Bucky table, X-Ray generator, portable wireless and fixed detectors) which is the same as the predicate Ysio. The Indication For Use remains unchanged compared to the predicate Ysio. The changes to the predicate Ysio include:

- A new detector generation by the same manufacturer (Trixell): one integrated detector sized 43x43cm and two wireless detectors in sizes 35x43cm and 24x30cm. The new detector generation offers improved options for the clinician and the patient with three sizes of image capability with two of the detectors portable/wireless in two size options. The smaller detector, MAX Mini, is optimal for smaller images of the hand or foot for example.
- New system control software, which realizes Free Axis Simultaneous Travel (FAST) in up to 6 axes at the same time supported by 8 individual motors. This feature, along with the AIM (Artificial Intelligence Mapping) feature is designed to calculate the shortest, fastest and safest path from one position to the next, in safe and efficient way. These features are present in the predicate Ysio, but improvements in the software performance allow for simultaneous movements in multiple axis in the subject device. This increases workflow efficiency in positioning the equipment for different examinations.
- The option to process images with Riverain ClearRead (formerly SoftView), which provides a soft tissue image for digital chest X-rays. ClearRead from Riverain Medical has its own 510(k) K092363 which was cleared on March 18, 2010. This feature for image processing was available in the predicate Ysio as an option. In this 510(k) this imagine processsing package is established as an optional configuration for the subject device.
- Ergonomic mechanical improvement which includes new handgrips for the Bucky wall stand.

These modifications to the device do not have an effect on safety and effectiveness compared to the predicate Ysio.

9. Performance Testing:

Siemens claims conformance in signed Statements of Conformance to recognized performance standards. This submission contains performance data to demonstrate continued conformance with special controls for medical devices containing software. Non clinical tests (integration and functional) were conducted on the software during product development. The Risk Analysis was completed and risk control implemented to

mitigate any identifed hazards. The testing results supports that all software specifications have met the acceptance criteria.

Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.
EMC/electrical safety was evaluated according to the IEC Standards. Siemens certifies conformance to Voluntary Standards covering Electrical and Mechanical Safety.
In conclusion, the identified risk of electrical hazards was mitigated and is substantially equivalent to the predicate device Ysio in terms of safety and effectiveness.

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirement Specification Reviews
- Design Reviews
- Integration testing (System verification)

10. Summary of Clinical Tests:

Clinical testing was not applicable as Ysio Max has no new or changed Indications for Use nor any new clinical applications were introduced with the modified system.

11. 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. Several safety features including visual and audible warnings are incorporated into the system design. In addition the **Ysio Max** Radiography X-Ray system is continually monitored, and if an error occurs, the system functions will be blocked and an error message will be displayed.

Furthermore the operators are health care professionals familiar with and responsible for the X-Ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practices, and all equipment is subject to final performance testing.

12. Conclusion as to Substantial Equivalence:

The Ysio Max is intended for the same indication for use as the predicate Ysio. The operating environment is the same and mechanical design similar. It is Siemens opinion, that the Ysio Max is substantially equivalent to the Ysio, cleared 8/25/2008 with K081722.

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

January 24, 2014

Siemens Medical Solutions USA, Inc.
% Mr. Darren Dorman
Regulatory Affairs Specialist
51 Valley Stream Parkway
MALVERN PA 19355

Re: K133259
Trade/Device Name: Ysio Max
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: December 23, 2013
Received: December 26, 2013

Dear Mr. Dorman:

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.

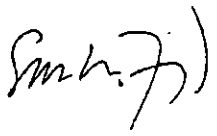
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
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): K133259

Device Name: Ysio Max

Indications for Use:

The Ysio Max is a radiographic system used in hospitals, clinics, and medical practices. Ysio Max enables radiographic and tomographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. It can also be used for intravenous, small interventions (like biopsy, punctures, etc.) and emergency (trauma, critical ill) applications. Exposures may be taken with the patient sitting, standing, or in the prone position. The Ysio Max system is not meant for mammography.

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Prescription Use __X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

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