K081722

AUG 25 2008

SECTION 5

510(k) Summary
FOR
SIEMENS Ysio

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

June 12, 2008

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.

1. **Contact Person:**
Mr. Gary Johnson
Technical Specialist, Regulatory Affairs Submissions
Siemens Medical Solutions USA, Inc
51 Valley Stream Parkway E-50
Malvern, PA 19355-1406
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2. **Device Name and Classification**

Trade Name:	Ysio
Classification Name:	Solid State X-ray Imager (SSXI)
Classification:	Panel: Radiology
CFR Section:	21 CFR §892.1680
Device Class:	Class II
Device Code:	90MQB

3. **Intended Use:**
The Ysio (New RAD –FAMILY) systems are radiographic systems used in hospitals, clinics, and medical practices. Ysio 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 system is not meant for mammography.
The Ysio uses an integrated or portable digital detector for generating diagnostic images by converting x-rays into electronic signals. Ysio is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.

4. Device Description:

The Ysio Radiography X-ray system is designed as a set of components such as ceiling suspension, bucky wall stand, bucky table, X-ray generator, X-ray tube, a portable wireless and a fixed detector, that may be combined into different configurations to provide specialized customer requirements.
The Ysio Radiography X-ray system is based on the currently available medical devices as listed in section 5.

5. Substantial Equivalence:

The **Ysio** Radiography x-ray system is designed with a portable wireless and a fixed detector. The new ceiling mounted configuration allows acquisition of radiographic exposures of various anatomical regions of the body. It is substantially equivalent to the following SIEMENS Medical Systems devices:

510(k) Number	Date of Clearance	Device Name
K983732	April 21, 1999	Thorax FD and Multix FD (AXIOM Aristos TX / MX)
K061054	May 09, 2006	AXIOM Aristos FX Plus (Wireless Remote)
K062623	August 22, 2007	AXIOM Luminos dRF

Many of the components used on the Ysio i.e. x-ray generator, x-ray tube, user interface, displays are used from already cleared medical devices. Some components i.e. collimator, flat detector, digital imaging system and tables include same or improved functionality.

The Wireless Interface of the mobile detector is substantially equivalent to the wireless interface of the Krystal-X WiFi wireless digital X-ray sensor from Video Dental Concepts, Inc.

510(k) Number	Date of Clearance	Device Name
K070505	April 5, 2007	Krystal-X WiFi

A detailed Substantial Equivalence Comparison is provided in Section 12.

6. **Summary of Technological Characteristics of the Principal Device as compared with the Predicate Device:**

The **Ysio** Radiography X-ray system is designed as a set of components (ceiling suspension, bucky wall stand, bucky table, X-ray generator, X-ray tube, a portable wireless and a fixed detector etc.) that may be combined into different configurations to provide specialized customer requirements. Many of the components used with **Ysio** are either commercially available with current Siemens systems or include minor modifications to existing components.

7. **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** 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 practice, and all equipment is subject to final performance testing.

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

Mr. Gary Johnson
Regulatory Technical Specialist
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51 Valley Stream Parkway E-50
MALVERN PA 19355-1406

AUG 21 2013

Re: K081722
Trade/Device Name: YSIO
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray System
Regulatory Class: II
Product Code: KPR
Dated: June 17, 2008
Received: June 28, 2008

Dear Mr. Johnson:

This letter corrects our substantially equivalent letter of August 25, 2008.

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,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

SECTION 4

INDICATIONS FOR USE

510(k) Number (if known):_____
Device Name: YSIO

Indications for Use:

The Ysio (New RAD –FAMILY) systems are radiographic systems used in hospitals, clinics, and medical practices. Ysio 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 system is not meant for mammography.

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

Prescription Use ✓ 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 Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081722