June 13, 2018

Siemens Medical Solutions, Inc.
% Ms. Denise Adams
Regulatory Affairs Specialist
40 Liberty Boulevard 65-1A
MALVERN PA 19355

Re: K181279
Trade/Device Name: Ysio Max
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: May 14, 2018
Received: May 15, 2018

Dear Ms. Adams:

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.

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/) and CDRH Learn (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) for more information or contact DICE by email (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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181279

Device Name
Ysio Max

Indications for Use *(Describe)*
Ysio Max is a device intended to visualize anatomical structures by converting an X-ray pattern into a visible image. Ysio Max enables radiographic and tomographic exposures of the whole body and may be used on pediatric, adult and bariatric patients. It can also be used for emergency applications.

Ysio Max is not for mammography examinations.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Special 510(k) Summary: Ysio Max

Company:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355

Date Prepared: June 12, 2018

This 510(k) summary of safety and effectiveness information is being submitted in accordance with 21 CFR § 807.92.

1. **General Information:**

   Importer / Distributor:
   Siemens Medical Solutions USA, Inc.
   40 Liberty Boulevard
   Malvern, PA 19355
   Establishment Registration Number: 2240869

   Location of Manufacturing Site:
   Siemens Healthcare GmbH
   Siemensstr. 1
   91301 Forchheim, Germany
   Establishment Registration Number: 3004977335

2. **Contact Person:**
   Denise Adams, RAC
   Regulatory Affairs Specialist
   Siemens Medical Solutions USA, Inc.
   40 Liberty Boulevard, 65 – 1A
   Malvern, PA 19355
   adams.denise@siemens-healthineers.com

   Alternate Contact Person:
   Patricia D. Jones
   Regulatory Affairs Specialist
   Siemens Medical Solutions USA, Inc.
   40 Liberty Boulevard, 65 – 1A
   Malvern, PA 19355
   patricia.d.jones@siemens-healthineers.com

3. **Device Name and Classification:**

   Trade Name: Ysio Max

Classification Name: Stationary x-ray System
Classification Panel: Radiology
Classification Regulation: 21 CFR §892.1680
Device Class: II
Product Codes: KPR

4. **Legally Marketed Predicate Device:**

Trade Name: Ysio Max
510(k) Number: K133259
Device Classification Name: Stationary x-ray System
Regulation Medical Specialty: Radiology
Review Panel: Radiology
Product Code: KPR
Submission Type: Special 510(k)
Regulation Number: 892.1680
Device Class: II

5. **Device Description:**

The Ysio Max is a stationary X-ray system for radiography. The main components are the X-ray generator, the X-ray tube with collimator supported by a ceiling rail system. The Ysio Max comes with SSXIs (Solid State X-ray Imagers) that can be mobile or fixed in the Bucky tray. An image processing and data management system (*syngo* FLC) completes the radiographic suite.

The purpose of this submission is the upgrade to a new software version VF10 and minor hardware changes. The modified Yisio Max will introduce the following new features:

- The operating system will be MS Windows 10
- New cybersecurity features
- Additional pediatric programs
- Implementing a "Virtual Machine" that supports hospital IT
- The SSXIs have been updated
- The EMC (Electromagnetic Compatibility was tested according to the IEC 4th edition)
- The image processing algorithms (Diamond view Plus) will be used for exposures without grid.

6. **Indications for Use:**

Ysio Max is a device intended to visualize anatomical structures by converting an X-ray pattern into a visible image. Ysio Max enables radiographic and tomographic exposures of the whole body and may be used on pediatric, adult and bariatric patients. It can also be used for emergency applications.

Ysio Max is not for mammography examinations**.**

7. **Substantial Equivalence:**
The new system software VF10 does not alter the intended use or the fundamental scientific technology. The device remains within the same classification regulation for the same intended use as the predicate device. The new system software design was completed in accordance with Siemens Quality Management System Design Controls comparable to the processes available for the predicate device. The scope of internationally recognized standards compliance was updated to the standards recognized at the time of the design of the new software. Verification and Validation testing was the same or similar to the testing being used with the predicate device.

The new system software version VF10 controls solid state X-ray imagers (SSXI) similar to the imagers being used with the predicate device. The updated MAX wi-D and Max mini detectors have been previously cleared in K173639.

8. **Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:**
The subject device with the new software version VF10 uses the same X-ray generator, the same X-ray tube and similar SSXIs with the same digital imaging system and similar image processing software as the predicate device. There are no changes in the patient environment or the type of user interface.

The following tables compare the main performance data of the subject device with the predicate device to substantiate equivalence.

Table 1: Comparison of the Subject Device Ysio Max to the Predicate

	Subject Device	Predicate Device	
Feature	**Ysio Max**	**Ysio Max K133259**	**Comparison Results**
Indications for Use Comparison			
Indications for Use statement	Ysio Max is a device intended to visualize anatomical structures by converting an X-ray pattern into a visible image. Ysio Max enables radiographic and tomographic exposures of the whole body and may be used on pediatric, adult and bariatric patients. It can also be used for emergency applications. Ysio Max is not for mammography examinations**.**	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.	Intended use is the same. Indications for use have been reworded to simplify.

Technical Comparison			
X-ray			
Generator	Polydoros 65/80 kW	Polydoros 65/80 kW	Same
X-ray tube	OPTITOP 150/40/80/HC-100	OPTITOP 150/40/80/HC-100	
Collimator	Digital Multileaf Collimator N	Digital Multileaf Collimator N	
Air kerma	Kerma X	Kerma X	
X-ray techniques	Radiography	Radiography	
Organ programs	X-ray parameters Imaging processing parameters	X-ray parameters Imaging processing parameters	
Testing			
IEC Compliance	IEC 4th edition for EMC testing	IEC 3rd edition for EMC testing	Testing according to current IEC test scope
Digital Imaging			
SSXI for Rad imaging	Trixell Pixium MAX wi-D = 3543EZh MAX mini = 2430EZ MAX Static = 4343RC	Trixell Pixium MAX wi-D = 3543EZh MAX mini = 2430EZ MAX Static = 4343RC	Image Chain is similar to predicate device Detector Performance data according To SSXI guidance are provided
Digital imaging system	Fluorospot Compact aka *syngo* FLC	Fluorospot Compact	
Image processing	Diamond View Plus	Diamond View Plus	Same processing made user friendly
MS Operating system	Windows 10	Windows 7	New Operating system
Cybersecurity	Security package based on MS Win 10	Security package based on MS Win 7	Improved
Integration of hospital IT	Hospital/Radiology Information System	Hospital/Radiology Information System	Improved
Pediatric package	Increased number of organ programs	Organ programs	Increased number and variability

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Table 2: Comparison of Trixell Pixium 4343RCE to the predicate Pixium 4343RC (MAX static)

Technical Specifications	Trixell Pixium 4343RCE detector (MAX static) (fixed) (subject)	Trixell Pixium 4343RC detector (fixed) (predicate)	Comparison Results
Dimensions	423.3mm x 425.4 mm	424.6 mm x 425.5 mm	Difference not significant
Resolution	2860 x 2874 pixels	2869 x 2874 pixels	Difference not significant
Pixel size	148 µm	148 µm	Same
Semiconductor Material	Amorphous silicon, a-Si	Amorphous silicon, a-Si	Same
Scintillator	Cesium iodide (CsI)	Cesium iodide (CsI)	Same
Acquisition depth	16 bit	16 bit	Same
DQE (Detective Quantum Efficiency)	DQE @ 0.05 lp/mm (2 µGy), 67%	DQE @ 0.05 lp/mm (2 µGy), 65%	Difference not significant
MTF (Modulations transfer function)	MTF @ 1 lp/mm, 62%	MTF @ 1 lp/mm, 63%	Difference not significant

Table 3: Comparison of Trixell Pixium 3543 EZh to the predicate Pixium 3543EZh (MAX wi-D)

Technical Specifications	Trixell Pixium 3543 EZh detector (wireless)(subject)	Trixell Pixium 3543 EZh detector (MAX wi-D) (wireless) (predicate)	Comparison Results
Dimensions	348 mm x 424 mm	349 mm x 425 mm	Difference not significant
Resolution	2350 x 2866 pixels	2356 x 2872 pixels	Difference not significant
Pixel size	148 µm	148 µm	Same
Semiconductor Material	Amorphous silicon, a-Si	Amorphous silicon, a-Si	Same
Scintillator	Cesium iodide (CsI)	Cesium iodide (CsI)	Same
Acquisition depth	16 bit	16 bit	Same
DQE (Detective Quantum Efficiency)	DQE @ 1 lp/mm (2 µGy), 51%	DQE @ 1 lp/mm (2 µGy), 50%	Difference not significant
MTF (Modulations transfer function)	MTF @ 1 lp/mm,63%	MTF @ 1 lp/mm,61%	Difference not significant

Table 4: Comparison of Trixell Pixium 2430 EZ to the predicate Pixium 2430 EZ (MAX mini)

Technical Specifications	Trixell Pixium 2430 EZ detector (wireless) (subject)	Trixell Pixium 2430 EZ detector (MAX mini) (wireless) (predicate)	Comparison Results
Dimensions	225 mm x 284 mm	228 mm x 284 mm	Difference not significant
Resolution	1520 x 1920 pixels	1560 x 1920 pixels	Difference not significant
Pixel size	148 µm	148 µm	Same
Semiconductor Material	Amorphous silicon, a-Si	Amorphous silicon, a-Si	Same
Scintillator	Cesium iodide (CsI)	Cesium iodide (CsI)	Same
Acquisition depth	16 bit	16 bit	Same
DQE (Detective Quantum Efficiency)	DQE @ 1 lp/mm (2 µGy), 50%	DQE @ 1 lp/mm (2 µGy), 50%	Same
MTF (Modulations transfer function)	MTF @ 1 lp/mm,61%	MTF @ 1 lp/mm,61%	Same

Summary of Non-Clinical Test Data:
The software VF10 design was completed in accordance with Siemens Quality Management System Design Controls and verification and validation testing were successfully conducted. Non-clinical performance data are provided for the updated detectors. The new IEC 4th edition has been applied for the compliance to the IEC 60601-1-2 electromagnetic compatibility standard.

The tests were performed on the new software VF10 demonstrating that the device is safe and effective, performs comparably to the predicate device, and is substantially equivalent to the predicate device.
Documentation provided demonstrates compliance of the subject device to all FDA requirements stated in the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, including results of verification/validation tests of software requirements and software risk hazards.
Performance testing confirmed that the five devices comply with 21 CFR 1020.30-31 Federal Performance Standards for X-Ray Fluoroscopic equipment

The software VF10 controls solid state X-ray imagers (SSXI) that are similar in performance to the predicates. Performance data are provided according to the "Guidance

for the Submission of 510(k)'s for Solid State X-ray Imaging Devices, issued on: September 1, 2016". X-ray geometry and techniques are the same so that clinical image comparisons involving SSXI were not conducted.
Together, the verification/validation activities successfully confirmed that the software requirements have been fulfilled and that system functionality is consistent with the user needs and intended uses. The VF10 software correctly performs as designed and raises no new questions regarding safety or effectiveness. Therefore, when compared to the predicate device the Ysio Max with the new software VF10 support a determination of substantial equivalence to the predicate device.

9. Summary of Non-Clinical Tests

The devices operating with software VF10 comply with the voluntary standards as listed in the following table:

Table 5: Standards

Development Organization and Reference Number	Title of Standard
IEC 60601-1:2012, Edition 3.1	Medical Electrical Equipment - Part 1: General Requirements for Safety
IEC 60601-1-2:2007 Edition 4.0	Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests
IEC 60601-1-3: 2012, Edition 2.1	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 62366:2014 Edition 1.1	Medical devices – Application of usability engineering to medical devices
ISO 14971, 2007	Medical devices – application of risk management to medical devices
IEC 62304 Ed. 1.0, 2006	Medical device software - Software life cycle processes
IEC 60601-2-28:2010 Edition 2.0	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
IEC 60601-2-54, 2009 Edition 1.0	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
IEC 61910-1, 2014	Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy (IEC 61910-1:2014)

NEMA PS 3.1 - 3.20, 2011	Digital Imaging and Communications in Medicine (DICOM) Set
ISO 10993-1, 2009	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

Documentation provided demonstrates compliance of the subject devices to all FDA requirements stated in the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, including results of verification/validation tests of software requirements and software risk hazards.

Performance testing confirmed that the Ysio Max with VF10 complies with 21 CFR 1020.30-31 Federal Performance Standards for X-Ray equipment. The applicable sections include:

1020.30(c)	Manufacturer's Responsibility (Certification)
1020.30(e)	Identification of X-ray components
1020.30(g)	Information to be provided to assemblers
1020.30(h)	Information to be provided to users
1020.31(k)	Leakage Radiation
1020.30(m)	Beam Quality
1020.31(a)	Peak Tube Potential
1020.31 (d)(2)(i, iii)	Alignment of visually defined X-ray fields and contrast of light defined X-ray field.
1020.31 (e)(1)(i)	Alignment of the center of the radiographic X-ray field with the center of the image receptor
1020.31 (e)(1)(ii, iii)	Radiography X-ray field size and image receptor size

The software VF10 controls solid state X-ray imagers (SSXI) that are similar in performance to the predicates. Performance data are provided according to the "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices, issued on: September 1, 2016".

10. Summary of Clinical Tests:

For the subject of this premarket submission, Siemens did not do an evaluation of the clinical image quality as X-ray technology; geometry and SSXI changes are minor.

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 devices are 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.

12. Conclusion as to Substantial Equivalence:

The Ysio Max with VF10 software has the same intended use as the predicate device. The operating environment is the same and the technology differences do not affect safety and effectiveness. Siemens concludes via the documentation provided in this 510(k) submission that the radiology device Ysio Max with VF10 is substantially equivalent to the predicate device Ysio Max.

13. Guidance documents

The following FDA guidance documents were utilized in the documentation of this Premarket Notification:

- Guidance for Industry and FDA Staff

Bundling Multiple Devices or Multiple Indications in a Single Submission
Document issued on: June 22, 2007

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

Guidance for Industry and Food and Drug Administration Staff
Document Issued on: October 2, 2014

- Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices

Guidance for Industry and Food and Drug Administration Staff
Document issued on July 11, 2016.
The draft of this document was issued on November 2, 2015.

- Pediatric Information for X-ray

Imaging Device Premarket Notifications
Guidance for Industry and Food and Drug Administration Staff
Document issued on November 28, 2017.

- Guidance for the Submission of 510(k)s for

Solid State X-ray Imaging Devices 1
Guidance for Industry and Food and Drug Administration Staff
Document issued on: September 1, 2016

- Guidance for Industry and FDA Staff

Guidance for the Content of Premarket Submissions for Software contained in Medical Devices, Document issued on: May 11, 2005

- Guidance for Industry and FDA Staff

Recognition and Use of Consensus Standards
Document issued on: September 17, 2007

- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]

Guidance for Industry and Food and Drug Administration Staff
Document issued on: July 28, 2014

- Radio Frequency Wireless Technology in Medical Devices

Guidance for Industry and Food and Drug Administration Staff
Document issued on: August 14, 2013