Siemens Medical Solutions USA, Inc.
% Mr. Andrew Turner
Regulatory Affairs Specialist
40 Liberty Boulevard, 65-1A
MALVERN PA 19355

October 21, 2020

Re: K201670
Trade/Device Name: YSIO X.pree
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR
Dated: September 17, 2020
Received: September 21, 2020

Dear Mr. Turner:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201670

Device Name
YSIO X.Pree

Indications for Use *(Describe)*
The device is a digital X-ray system to generate X-ray images from the whole body including the skull, chest, abdomen, and extremities. The acquired images support medical professionals to make diagnostic and/or therapeutic decisions. Generic clinical benefits of radiographic examinations within the intended use are applicable for this device.

YSIO X.pree 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: YSIO X.pree

K201670

Company: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355

Date Prepared: August 5, 2020

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 USA, Inc.
40 Liberty Boulevard, 65-1A
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:

Andrew Turner
Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Mail Stop 65-1A
Malvern, PA 19355, USA
Phone: 610-850-5627
Email: andrew.turner@siemens-healthineers.com

3. Device Name and Classification:

Trade Name:	YSIO X.pree
Classification Name:	System, X-Ray, Stationary
Classification Panel:	Radiology
Classification Regulation:	21 CFR § 892.1680
Device Class:	Class II
Product Code:	KPR

4. Legally Marketed Predicate Device

Trade Name:	Ysio Max
510(k) #:	K181270
Classification Name:	System, X-Ray, Stationary
Classification Panel:	Radiology

Classification Regulation: 21 CFR §892.1680
Device Class: Class II
Product Code: KPR

5. Device Description:

The YSIO X.pree is a radiography X-ray system. It is designed as a modular system with components such as a 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 following modifications have been made to the cleared predicate device:

- New image system with touch user interface
- Added a camera at collimator to support clinical workflow

6. Indications for Use:

The device is a digital X-ray system to generate X-ray images from the whole body including the skull, chest, abdomen, and extremities. The acquired images support medical professionals to make diagnostic and/or therapeutic decisions. Generic clinical benefits of radiographic examinations within the intended use are applicable for this device.

YSIO X.pree is not for mammography examinations.

7. Substantial Equivalence:

The YSIO X.pree with VA10 is substantially equivalent to the commercially available Ysio Max VF10 (K181270).

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

The YSIO X.pree is comparable in indications for use, design, material, functionality, technology, energy source and is substantially equivalent to the commercially available Ysio Max. It uses the same or similar components cleared with Ysio Max (e.g. tube, collimator, table, wallstand, detector or generator).
Many components of the subject device have the same technological characteristics as those from the predicate device.
Testing and validation have been successfully completed and test results show that the subject device YSIO X.pree with all of its components is comparable and therefore substantially equivalent to the predicate device.
The modifications made to the subject device YSIO X.pree are within the scope of intended use of 510(k) cleared predicate device Ysio Max (tomographic exposure is no longer available) and they also don't alter the fundamental scientific technology compared to predicate device.

Table 1: Comparison of the Subject to the Predicate

Attribute	Subject Device YSIO X.pree	Predicate Device Ysio Max K181279	Comparison / Remarks
Intended use	YSIO X.pree is a device intended to visualize anatomical structures by converting an X-ray pattern into a visible image. YSIO X.pree enables radiographic exposures of the whole body and may be used on pediatric, adult and bariatric patients. It can also be used for emergency applications. YSIO X.pree is not for mammography examinations.	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 option for tomographic exposures is not available for the subject device due to low customer use in previous devices. Ysio X.pree was initially developed without this feature and therefore this does not alter the safety and effectiveness.
Product Code	KPR	KPR	same
X-Ray			
Generator	Polydoros R80 65/80 kW	Polydoros R80 65/80 kW	same
X-Ray tube	OPTITOP 150/40/80/HC-100	OPTITOP 150/40/80/HC-100	same
X-ray techniques	Radiography	Radiography	same
Collimator	Digital Multileaf Collimator N	Digital Multileaf Collimator N	same
Air kerma	Kerma X	Kerma X	same
CARE	Combined Applications to Reduce Exposure	Combined Applications to Reduce Exposure	same
Touch user interface on tube suspension	New touchscreen in landscape format	Touchscreen in portrait format.	New touchscreen
Digital Imaging			
Fixed detector for table and wall stand	Trixell Pixium 4343RC “Max Static”	Trixell Pixium 4343RC “Max Static”	same
Large mobile detector	Trixell Pixium 3543EZh „MAX wi-D“	Trixell Pixium 3543EZh „MAX wi-D“	same
Small mobile detector	Pixium 2430EZ “MAX mini”	Pixium 2430EZ “MAX mini”	small changes in DQE and MTF, see table below, does not affect safety or

			effectiveness
Digital imaging system	syngo XR	Fluorospot Compact	Different, new imaging system
	Operating system Windows 10	Operating system Windows 10	same
	Operated via touch screen	Operated with mouse and keyboard	Different, does not affect safety or effectiveness
	Image processing with MyExam IQ	Image processing with Diamond View Plus	Slightly different, based on same processing software. Does not affect safety or effectiveness
	AI-based Auto Cropping	Auto Cropping	New Algorithm, does not affect safety or effectiveness
	Acquisition and Image processing parameters selected via clinical protocols	Acquisition and Image processing parameters selected via Organ Programs	Improved, does not affect safety or effectiveness
Other Features and Components			
Patient table	Table with fixed detector and table with bucky	Table with fixed detector and table with bucky	same
	Standard tabletop and flat tabletop	Standard tabletop	Additional flat tabletop for easier patient positioning, does not affect safety or effectiveness
Wall stand	Wall stand with fixed detector and wall stand with bucky	Wall stand with fixed detector and wall stand with bucky	same
Camera	Live camera for patient positioning and collimation	N/A	New, does not affect safety or effectiveness
Wireless Remote Control	Yes, same type	Yes, same type	same

Table 2: Comparison of detector parameters for detector Pixium 2430EZ

Mobile Rad detector	YSIO X.pree	Ysio Max / K181279
Siemens Name	MAX mini	MAX mini
Trixell name	Pixium 2430EZ	Pixium 2430EZ
Dimensions (active area)	28.4 cm x 22.5 cm	28.4 cm x 22.5 cm

Matrix size	1920 x 1520	1920 x 1520
DQE in %; 2 µGy	70 % at 0.05 lp/mm	66 % at 0.05 lp/mm
	51 % at 1 lp/mm	50 % at 1 lp/mm
	42 % at 2 lp/mm	40 % at 2 lp/mm
	29 % at 3 lp/mm	24 % at 3 lp/mm
	19 % at Nyquist	17 % at Nyquist
MTF in %	63 % at 1 lp/mm	61 % at 1 lp/mm
	35 % at 2 lp/mm	31 % at 2 lp/mm
	19 % at 3 lp/mm	15 % at 3 lp/mm
	15 % at Nyquist	12 % at Nyquist

The MAX mini has now the same image performance as the MAX Wi-D.

9. Summary of Non-Clinical Tests:

The YSIO X.pree was tested and complies with the voluntary standards listed in the table below:

Table 3: Non-clinical performance testing

Reference Number and Date	Title of Standard
IEC 60601-1 Edition 3.1 (IEC 60601-1:2005 + Cor.:2006 + Cor.:2007 + A1:2012)	Medical Electrical Equipment - Part 1: General Requirements for Safety
IEC 60601-1-2 Edition 4.0 (IEC 60601-1-2:2014)	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 Edition 2.1 (IEC 60601-1-3:2008 + A1:2013)	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-2-28 Edition 3.0 (IEC 60601-2-28: 2017)	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
IEC 60601-2-43 Edition 2.1 (IEC 60601-2-43:2010 + A1:2017)	Medical electrical equipment - Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures
IEC 60601-2-54 Edition 1.2 (IEC 60601-2-54:2009 + Cor.:2010 + Cor.:2011 + A1:2015 + A2:2018)	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

IEC 62366-1 Edition 1.0 (IEC 62366-1:2015)	Medical devices – Application of usability engineering to medical devices
ISO 14971:2019	medical devices – application of risk management to medical devices
IEC 62304 Edition 1.1 (IEC 62304: 2006 + A1:2015	Medical device software - Software life cycle processes
IEC 61910-1 Edition 1.0 (IEC 61910: 2014)	Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy (IEC 61910-1:2014)
PS 3.1 - 3.20 2016	Digital Imaging and Communications in Medicine (DICOM) Set
ISO 10993-1: 2013	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

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

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

10. 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 X.pree is continuously 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.

11. Conclusion as to Substantial Equivalence:

The YSIO X.pree has the same fundamental scientific technology and performance characteristics as the predicate, Ysio Max (K181270). The YSIO X.pree has the same intended use and a simplified indications for use. Therefore, the YSIO X.pree is substantially equivalent to the predicate Ysio Max

12. Guidance documents

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

- *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 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*