May 21, 2024

Siemens Medical Solutions USA, Inc.
% Camila Rodriguez Valentin
Regulatory Affairs Professional
40 Liberty Boulevard
Malvern, Pennsylvania 19355

Re: K233543
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: November 3, 2023
Received: April 24, 2024

Dear Camila Rodriguez Valentin:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Gabriela M. Rodal -S

Digitally signed by Gabriela M. Rodal -S

for

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233543

Device Name

YSIO X.pree

Indications for Use *(Describe)*

The intended use of the device YSIO X.pree is to visualize anatomical structures of human beings by converting an X-ray pattern into a visible image.

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.

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.

510(k) Summary: **YSIO X.pree**

510(k) Number: **K233543**

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

Date Prepared: May 20, 2024

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA of 1990 and 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 Healthineers AG
Siemensstr. 1
91301 Forchheim, Germany
Establishment Registration Number:
3004977335

2. Contact Person:

Camila Rodriguez Valentin
Regulatory Affairs Professional
Siemens Medical Solutions USA, Inc.40
Liberty Boulevard
Malvern, PA 19355, US
camila.rodriguezvalentin@siemens-healthineers.com

Alternate Contact Person:
Martin Rajchel
Senior Regulatory Affairs Manager
Siemens Medical Solutions USA, Inc.40
Liberty Boulevard
Malvern, PA 19355, US
martin.rajchel@siemens-healthineers.com

3. Subject Device Name and Classification:

Trade Name:	**YSIO X.pree**
Classification Name:	Stationary x-ray system
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	II
Product Code:	KPR

4. Legally Marketed Predicate Device:

Trade Name:	**YSIO X.pree**
Company:	Siemens Healthineers AG
510(k) Number:	K201670
Classification Name:	Stationary x-ray system
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	II
Product Code:	KPR

5. Legally Marketed Reference Device:

Trade Name:	**MULTIX Impact (VA21)**
Company:	Siemens Shanghai Medical Equipment Ltd.
510(k) Number:	K213700
Classification Name:	Stationary x-ray system
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	II
Product Code:	KPR

40 Liberty Boulevard
Malvern, PA 19355
USA

Tel.: +1-888-826-9702
usa.siemens.com/healthineers

6. 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 an 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 Camera Model in Collimator
- New Auto Collimation Function: Auto Long-Leg/Full-Spine
- Two new wireless detectors

7. Indication for Use:

The intended use of the device YSIO X.pree is to visualize anatomical structures of human beings by converting an X-ray pattern into a visible image.

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.

YSIO X.pree is not for mammography examinations.

8. Technological Characteristics and Substantial Equivalence:

The subject device is the same as the predicate device. The software was updated, and two new detectors have been added. The camera model for auto collimation was changed, and the reference device Multix Impact algorithm has been taken over. The new components and features have been tested and do not raise any new concerns of safety and effectiveness. The device remains within the same classification regulation for the same technology as the predicate device. The system software design was completed in accordance with Siemens Quality Management System Design Controls. The scope of internationally recognized standards compliance remains the same.

Table 8-1: Comparison of the Subject Device (YSIO X.pree VA20) to the PredicateDevice (YSIO X.pree VA10)

Feature	Predicate device YSIO X.pree VA10	Subject device YSIO X.pree VA20	Comment
Regulation Description	Stationary X-Ray System	Stationary X-Ray System	Same
Regulation Number	892.1680	892.1680	Same
Classification Product Code	KPR	KPR	Same
Indications for 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.	The intended use of the device YSIO X.pree is to visualize anatomical structures of human beings by converting an X-ray pattern into a visible image. 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. YSIO X.pree is not for mammography examinations.	Similar
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	touchscreen in landscape format	touchscreen in landscape format	Same
Digital Imaging			

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usa.siemens.com/healthineers

Feature	Predicate device YSIO X.pree VA10	Subject device YSIO X.pree VA20	Comment
Fixed detector for table and wall stand	Trixell pixium 4343RC "Max Static"	Trixell pixium 4343RC "Max Static"	Same
Large mobile detectors	Trixell pixium 3543EZh „MAX wi-D"	Trixell pixium 3543EZh „MAX wi-D"	Same
	N/A	**Trixell pixium 3543EZ3 "X.wi-D 35"**	**New for YSIO X.pree VA20**
	N/A	**Trixell pixium 4343EZ3 "X.wi-D 43"**	**New for YSIO X.pree VA20**
Small mobile detector	Trixell pixium 2430EZ "MAX mini"	Trixell pixium 2430EZ "MAX mini"	Same
Digital imaging system	syngo XR	syngo XR	Same
	Operating system Windows 10	Operating system Windows 10	Same
	Operated via touch screen	Operated via touch screen	Same
	Image processing with myExam IQ	Image processing with myExam IQ	Same
	AI-based Auto Cropping	AI-based Auto Cropping	Same
	Acquisition and Image processing parameters selected via clinical protocols	Acquisition and Image processing parameters selected via clinical protocols	Same
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 and flat tabletop	Same
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	Live camera for patient positioning and collimation	Similar New Camera Model, same functionality
AI based Automatic collimation	Auto Thorax Collimation	Auto Thorax Collimation	Different. Changed to new algorithm, Auto Long-Leg/Full-Spine collimation added
	N/A	Auto Long-Leg/Full-Spine collimation	
Cropping	AI-based auto cropping	AI-based auto cropping	Same
Wireless Remote Control	Yes, same type	Yes, same type	Same

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USA

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Table 8-2: Comparison of the Subject Device (YSIO X.pree VA20) to the Reference Device (Multix Impact) – AI based Automatic Collimation

Feature	Predicate device MULTIX Impact	Subject device YSIO X.pree VA20	Comment
Camera	Live camera for patient positioning and collimation	Live camera for patient positioning and collimation	Same The camera, used for MULTIX Impact, is now used for YSIO X.pree VA20
AI based Automatic collimation	Auto Thorax, Auto Long-Leg/Full-Spine collimation	Auto Thorax, Auto Long-Leg/Full-Spine collimation	Same The algorithm, used in MULTIX Impact, is also used for YSIO X.pree VA20

9. Summary of Non-Clinical Tests:

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

Table 9: Non-clinical performance testing

Standards Development Organization and Reference Number	Title of Standard
ANSI AAMI 60601-1, 2012 Ed. 3.1	Medical Electrical Equipment - Part 1: General Requirements for Safety
IEC 60601-1-2 2014 Ed 4.1	Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-3: Edition 2.1, 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, 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 60601-2-54 2018, Edition 1.2	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
IEC 60601-1-6 2020 Ed 3.2	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 62366-1 2020 Ed 1.1	Medical devices – Application of usability engineering tomedical devices
ISO 14971: 2019	Medical devices – application of risk management tomedical devices
IEC 62304 2015, Ed.1.1	Medical device software - Software life cycle processes
IEC 61910-1: 2014, Ed 1.0	Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy
NEMA PS 3.1 - 3.20 2021	Digital Imaging and Communications in Medicine(DICOM) Set
ISO EN ISO 10993-1 Fifth edition 2018	Biological evaluation of medical devices – Part1: 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. Summary of Clinical Tests:

A Customer Use Test (CUT) was performed at the "Universitätsklinikum Augsburg" in Augsburg, Germany, to ensure the acceptance of the design and to gather feedback on the usability of the device on the clinical environment.
The focus of the test was:

- System function and performance-related clinical workflow
- Image quality
- Ease of use
- Overall performance and stability

The results of the clinical test stated that the intended use of the system was met, and the clinical need covered.

11. General Safety and Effectiveness Concerns:

The Instructions for Use (IFU) are included within the device labeling, and the information provided enables the user to operate the device safely and effectively. Several safety features including visual and audible warnings are incorporated into the system design. In addition, the device 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.

12. Conclusion as to Substantial Equivalence:

The YSIO X.pree, that is the subject of this 510(k), is the same as the predicate device. The operating environment is the same and the changes do not affect safety and effectiveness. Siemens concludes, according to this submission material and the documentation provided, that the YSIO X.pree is substantially equivalent to the predicate device and reference device.

The newly introduced wireless detectors (X.wi-D35 and X.wi D43) were tested during a Clinical Use Test (CUT) at University Hospital Augsburg in Germany according to *"Guidance of Submission of 510(k)s for Solid State X-ray Imaging Devices" Document issued on: September 1, 2016.* All images acquired with the new detectors were sufficiently acceptable for radiographic usage. Together with the non-clinical testing, it has met the objective of demonstrating substantial equivalence when comparing the Siemens YSIO X.pree VA20 to the Siemens YSIO X.pree VA10 detectors.

13. Guidance documents

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

Provision for Alternate Measure of the Computed Tomography Dose Index (CTDI) to Assure Compliance with the Dose Information Requirements of the Federal Performance Standard for Computed Tomography
Document issued on October 20, 2006

Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submission - Guidance for Industry and Food and Drug Administration Staff
Document Issued on September 27, 2023

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

Content of Premarket Submissions for Device Software Functions - Guidance for Industry and FDA Staff
Document issued on June 14, 2023

Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices - Guidance for Industry and Food and Drug Administration Staff
Document issued on September 14, 2018.

The 510(k) Program: Evaluation Substantial Equivalent in Premarket Notifications 510(k) - Guidance for Industry and Food and Drug Administration Staff
Document issued on July 28, 2014.

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

Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff
Document issue on August 13, 2013