July 14, 2025

Siemens Medical Solutions
% Camila Rodriguez Valentin
Regulatory Affairs Professional
40 Liberty Boulevard
MALVERN, PA 19355

Re: K250660
Trade/Device Name: LUMINOS Q.namix T
LUMINOS Q.namix R
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA
Dated: March 5, 2025
Received: June 12, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Lu Jiang

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.

510(k) Number *(if known)*
K250660

Device Name
LUMINOS Q.namix T
LUMINOS Q.namix R

Indications for Use *(Describe)*

LUMINOS Q.namix T and LUMINOS Q.namix R are devices intended to visualize anatomical structures by converting an X-ray pattern into a visible image. It is a multifunctional, general R/F system, suitable for routine radiography and fluoroscopy examinations, including gastrointestinal- and urogenital examinations and specialist areas like arthrography, angiography and pediatrics.

LUMINOS Q.namix T and LUMINOS Q.namix R are not intended to be used 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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510(k) Summary

Trade Names: LUMINOS Q.namix T
LUMINOS Q.namix R

510(k) Number: **K250660**

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

Date Prepared: July 13, 2025

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
Sr. Regulatory Affairs Professional
Siemens Medical Solutions USA, Inc.
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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 Devices Names and Classification:

Trade Names:	LUMINOS Q.namix T LUMINOS Q.namix R
Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1650
Device Class:	II
Product Code:	OWB, JAA

4. Legally Marketed Predicate Devices:

Trade Names:	Luminos Agile Max Luminos dRF Max
510(k) Number:	K173639
Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1650
Device Class:	II
Product Code:	OWB, JAA

Reference Device:	
Trade Names:	YSIO X.pree
510(k) Number:	K233543
Classification Name:	Stationary x-ray system
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	II
Product Code:	KPR

5. Device Descriptions

The LUMINOS Q.namix T is an under-table fluoroscopy system and the LUMINOS Q.namix R is an over-table fluoroscopy system. Both systems are multifunctional, general R/F systems, suitable for routine radiography and fluoroscopy examinations, including gastrointestinal- and urogenital examinations and specialist areas like arthrography, angiography and pediatrics. They are designed as modular systems with components such as main fluoro table including fixed fluoroscopy detector and X-ray tube, a ceiling suspension with X-ray tube, Bucky wall stand, X-ray generator, monitors, a bucky tray in the table as well as portable wireless and fixed integrated detectors that may be combined into different configurations to meet specific customer needs.

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6. Indication for Use:

LUMINOS Q.namix T and LUMINOS Q.namix R are a devices intended to visualize anatomical structures by converting an X-ray pattern into a visible image. It is a multifunctional, general R/F system, suitable for routine radiography and fluoroscopy examinations, including gastrointestinal- and urogenital examinations and specialist areas like arthrography, angiography and pediatrics.

LUMINOS Q.namix T and LUMINOS Q.namix R are not intended to be used for mammography examinations.

7. Technological Characteristics and Substantial Equivalence

The LUMINOS Q.namix T/ LUMINOS Q.namix R systems are comparable in indications for use, design, material, functionality, technology, and energy source and are substantially equivalent to the commercially available LUMINOS Agile Max (under-table fluoroscopy system) and LUMINOS dRF Max (over- table fluoroscopy system). The subject devices do not alter the fundamental scientific technology compared to the predicate devices. The subject devices use the same or similar components cleared with predicate systems. Many components of the subject devices have the same technological characteristics as those from the predicate devices. Testing and validation have been successfully completed, and test results show that the subject devices LUMINOS Q.namix T and LUMINOS Q.namix R, with all of their components, are comparable and, therefore, substantially equivalent to the predicate devices.

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Table 7-1. Comparison of the Subject Device (LUMINOS Q.namix T) to the Predicate Device (Luminos Agile Max K173639)

Feature	Predicate device Luminos Agile Max	Subject device LUMINOS Q.namix T	Comment
Regulation Description	System, x-ray, fluoroscopic, image-intensified, Solid State X-ray imager	System, x-ray, fluoroscopic, image-intensified, Solid State X-ray imager	Same
Regulation Number	892.1650	892.1650	Same
Classification Product Code	JAA, OWB	JAA, OWB	Same
Indications for use	Luminos Agile Max is a device intended to visualize anatomical structures by converting an X-ray pattern into a visible image. The system has medical applications ranging from gastrointestinal examinations to cranial, skeletal, thoracic and lung exposures as well as examinations of the urogenital tract. The unit may also be used in emergency applications, lymphography, endoscopy, myelography, venography, arthrography, interventional radiology, digital angiography and digital subtraction angiography (DSA). The system may be used on pediatric, adult and bariatric patients. Luminos Agile Max is not for mammography examinations.	LUMINOS Q.namix T and LUMINOS Q.namix R are devices intended to visualize anatomical structures by converting an X-ray pattern into a visible image. It is a multifunctional, general R/F system, suitable for routine radiography and fluoroscopy examinations, including gastrointestinal- and urogenital examinations and specialist areas like arthrography, angiography and pediatrics. LUMINOS Q.namix T and LUMINOS Q.namix R are not intended to be used for mammography examinations.	Similar
X-Ray			
Generator	Polydoros F80 65/80 kW	Polydoros RFX 65/80 kW	Changed, new State of the Art Generator
X-Ray tube	OPTITOP 150/40/80/HC-100	OPTITOP 150/40/80/HC-100	Same
X-ray techniques	Radiography, Pulsed fluoroscopy, DSA and series exposure	Radiography, Pulsed fluoroscopy and series exposure	Changed, DSA function is not available at LUMINOS

Feature	Predicate device Luminos Agile Max	Subject device LUMINOS Q.namix T	Comment
			Q.namix T
Collimator	Digital Multileaf Collimator N	Digital Multileaf Collimator RFU	Changed, new collimator
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 portrait format	touchscreen in landscape format	Changed, same touch user interface as for reference device YSIO X.pree is used
Controls at Digital Imaging Tower (DIT)	hardware buttons	Two touch user interfaces at left and right side, replacing most of the hardware buttons	Changed, new touch user interface
Digital Imaging			
Fluoro Detector in DIT	Trixel pixium 4343F-4 “Max Dynamic”	Trixel pixium 4343F-5 “X.fluoro”	Changed, new version of the Fluoro detector
Fixed detector for wall stand	Trixell pixium 4343RCE “Max Static”	Trixell pixium 4343RCE “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, Same as for reference device YSIO X.pree.
	N/A	Trixell pixium 4343EZ3 “X.wi-D 43”	New, Same as for reference device YSIO X.pree.
Small mobile detector	Trixell pixium 2430EZ “MAX mini”	Trixell pixium 2430EZ “MAX mini”	Same
	N/A	Trixell pixium 2430EZ3 “X.wi-D 24”	New for LUMINOS Q.namix T
Digital imaging system	Fluorospot Compact	Fluorospot Compact Plus	Changed
	Operating system Windows 10	Operating system Windows 10	Same
	Operated via mouse and keyboard	Operated via touch screen	Changed
	Image processing with Diamond View Plus	Image processing with myExam IQ	Slightly different, based on same processing software. Same as for reference device YSIO X.pree.
	N/A	AI-based Auto Cropping	New, Same as for reference device YSIO X.pree.
	Acquisition and Image processing parameters selected via Organ Programs	Acquisition and Image processing parameters selected via clinical protocols	Changed, same as for reference device YSIO X.pree.
Display	19” Monitor	24” and 32” Touch Monitors	Changed, new touch Monitors available

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Feature	Predicate device Luminos Agile Max	Subject device LUMINOS Q.namix T	Comment
Other Features and Components			
Ceiling Stand (Second Plane)	Ysio Max Ceiling Stand	YSIO X.pree Ceiling Stand	Changed, updated Ceiling Stand
Patient Table	Table with optional bucky tray	Table with optional bucky tray	Same
	Standard tabletop	Standard tabletop and flat tabletop	Changed, optional flat tabletop is now available
Wall stand	Wall stand with fixed detector and wall stand with bucky tray	Wall stand with fixed detector and wall stand with bucky tray	Same
Camera	N/A	Live camera for patient positioning and collimation	New, Same as for reference device YSIO X.pree.
AI based Automatic collimation	N/A	Auto Thorax, Auto Long-Leg/Full-Spine collimation	New, Same as for reference device YSIO X.pree.
Cropping	Auto Cropping	AI-based Auto Cropping	Changed, same AI-based cropping used as for reference device YSIO X.pree.
Indicator Lights	N/A	Indicator Light at tube stand (YSIO X.pree option)	New
Light below Digital Imaging Tower (DIT)	N/A	available	New
Foot Switch	Wired Footswitch	Wired and wireless Footswitch	New wireless foot switch

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Table 7-2. Comparison of the Subject Device (LUMINOS Q.namix R) to the Predicate Device (Luminos dRF Max K173639)

Feature	Predicate device Luminos dRF Max	Subject device LUMINOS Q.namix R	Comment
Regulation Description	System, x-ray, fluoroscopic, image-intensified, Solid State X-ray imager	System, x-ray, fluoroscopic, image-intensified, Solid State X-ray imager	Same
Regulation Number	892.1650	892.1650	Same
Classification Product Code	JAA, OWB	JAA, OWB	Same
Indications for use	Luminos dRF Max is a device intended to visualize anatomical structures by converting an X-ray pattern into a visible image. The system has medical applications ranging from gastrointestinal examinations to cranial, skeletal, thoracic and lung exposures as well as examinations of the urogenital tract. The unit may also be used in emergency applications, lymphography, endoscopy, myelography, venography, arthrography, interventional radiology, digital angiography and digital subtraction angiography (DSA). The system may be used on pediatric, adult and bariatric patients. Luminos dRF Max is not for mammography examinations.	LUMINOS Q.namix T and LUMINOS Q.namix R are devices intended to visualize anatomical structures by converting an X-ray pattern into a visible image. It is a multifunctional, general R/F system, suitable for routine radiography and fluoroscopy examinations, including gastrointestinal- and urogenital examinations and specialist areas like arthrography, angiography and pediatrics. LUMINOS Q.namix T and LUMINOS Q.namix R are not intended to be used for mammography examinations.	Similar
X-Ray			
Generator	Polydoros F80 65/80 kW	Polydoros RFX 65/80 kW	Changed, new State of the Art Generator
X-Ray tube	OPTITOP 150/40/80/HC-100	OPTITOP 150/40/80/HC-100	Same
X-ray techniques	Radiography, Pulsed fluoroscopy, DSA and series exposure	Radiography, Pulsed fluoroscopy and series exposure	Changed, DSA function is not available at LUMINOS

Feature	Predicate device Luminos dRF Max	Subject device LUMINOS Q.namix R	Comment
			Q.namix R
Collimator	Digital Multileaf Collimator N	Digital Multileaf Collimator RFU	Changed, new collimator
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 portrait format	touchscreen in landscape format	Changed, same touch user interface as for reference device YSIO X.pree is used
Digital Imaging			
Fluoro Detector in table	Trixel pixium 4343F-4 "Max Dynamic"	Trixel pixium 4343F-5 "X.fluoro"	Changed, new version of the Fluoro detector
Fixed detector for wall stand	Trixell pixium 4343RCE "Max Static"	Trixell pixium 4343RCE "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, Same as for reference device YSIO X.pree.
	N/A	Trixell pixium 4343EZ3 "X.wi-D 43"	New, Same as for reference device YSIO X.pree.
Small mobile detector	Trixell pixium 2430EZ "MAX mini"	Trixell pixium 2430EZ "MAX mini"	Same
	N/A	Trixell pixium 2430EZ3 "X.wi-D 24"	New for LUMINOS Q.namix R
Digital imaging system	Fluorospot Compact	Fluorospot Compact Plus	Changed
	Operating system Windows 10	Operating system Windows 10	Same
	Operated via mouse and keyboard	Operated via touch screen	Changed
	Image processing with Diamond View Plus	Image processing with myExam IQ	Slightly different, based on same processing software. Same as for reference device YSIO X.pree.
	N/A	AI-based Auto Cropping	New, Same as for reference device YSIO X.pree.
	Acquisition and Image processing parameters selected via Organ Programs	Acquisition and Image processing parameters selected via clinical protocols	Changed, same as for reference device YSIO X.pree.
Display	19" Monitor	24" and 32" Touch Monitors	Changed, new touch Monitors available
Other Features and Components			
Ceiling Stand (Second Plane)	Ysio Max Ceiling Stand	YSIO X.pree Ceiling Stand	Changed, updated Ceiling Stand
Patient Table	Table with optional bucky tray	Table with optional bucky tray	Same
	Standard tabletop	Standard tabletop and flat	Changed, optional flat

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Feature	Predicate device Luminos dRF Max	Subject device LUMINOS Q.namix R	Comment
		tabletop	tabletop is now available
Wall stand	Wall stand with fixed detector and wall stand with bucky tray	Wall stand with fixed detector and wall stand with bucky tray	Same
Camera	N/A	Live camera for patient positioning and collimation	New, Same as for reference device YSIO X.pree.
AI based Automatic collimation	N/A	Auto Thorax, Auto Long-Leg/Full-Spine collimation	New, Same as for reference device YSIO X.pree.
Cropping	Auto Cropping	AI-based Auto Cropping	Changed, Same AI-based cropping used as for reference device YSIO X.pree.
Indicator Lights	N/A	Indicator Light at tube stand (YSIO X.pree option)	New for LUMINOS Q.namix R
Mood Light	N/A	Available	New for LUMINOS Q.namix R
Foot Switch	Wired Footswitch	Wired and wireless Footswitch	New wireless foot switch

Table 7-3. Comparison of the Subject Devices (LUMINOS Q.namix T) to the Reference Device (YSIO X.pree, K 233543)

Feature	Reference device YSIO X.pree	Subject device LUMINOS Q.namix T	Comment
Camera	Live camera for patient positioning and collimation	Live camera for patient positioning and collimation	Same
AI based Automatic collimation	Auto Thorax, Auto Long-Leg/Full-Spine collimation	Auto Thorax, Auto Long-Leg/Full-Spine collimation	Same
Cropping	AI-based Auto Cropping	AI-based Auto Cropping	Same
Digital imaging system	Image processing with myExam IQ	Image processing with myExam IQ	Same
	Acquisition and Image processing parameters selected via clinical protocols	Acquisition and Image processing parameters selected via clinical protocols	Same
Large mobile detectors	Trixell pixium 3543EZ3 “X.wi-D 35”	Trixell pixium 3543EZ3 “X.wi-D 35”	Same
	Trixell pixium 4343EZ3 “X.wi-D 43”	Trixell pixium 4343EZ3 “X.wi-D 43”	Same

Table 7-4. Comparison of the Subject Devices (LUMINOS Q.namix R) to the Reference Device (YSIO X.pree, K 233543)

Feature	Reference device YSIO X.pree	Subject device LUMINOS Q.namix R	Comment
Camera	Live camera for patient positioning and collimation	Live camera for patient positioning and collimation	Same
AI based Automatic collimation	Auto Thorax, Auto Long-Leg/Full-Spine collimation	Auto Thorax, Auto Long-Leg/Full-Spine collimation	Same
Cropping	AI-based Auto Cropping	AI-based Auto Cropping	Same
Digital imaging system	Image processing with myExam IQ	Image processing with myExam IQ	Same
	Acquisition and Image processing parameters selected via clinical protocols	Acquisition and Image processing parameters selected via clinical protocols	Same
Large mobile detectors	Trixell pixium 3543EZ3 "X.wi-D 35"	Trixell pixium 3543EZ3 "X.wi-D 35"	Same
	Trixell pixium 4343EZ3 "X.wi-D 43"	Trixell pixium 4343EZ3 "X.wi-D 43"	Same

Table 7.5. Additional Comparison of Subject Devices (LUMINOS Q.namix T and LUMINOS Q.namix R) to Predicate Devices (Luminos dRF Max and Luminos Agile Max)

System / Function	Luminos Agile Max (Predicate)	Luminos dRF Max (Predicate)	LUMINOS Q.namix T	LUMINOS Q.namix R
Fluoroscopy outside of the Examination Room		X		X
Fluoroscopy at the table next to the patient	X		X	
Tube over the table		X		X
Tube under the table	X		X	
Second Plane YSIO X.pree (option)			X	X
Second Plane Ysio Max (option)	X	X		

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8. Summary of Non-Clinical Tests:

The LUMINOS Q.namix T/LUMINOS Q.namix R systems were tested and comply with the voluntary standards listed in the table below:

Table 8. Non-clinical performance testing

Standards Development Organization and Reference Number	Title of Standard
ANSI AAMI 60601-1, 2020 Ed. 3.2	Medical Electrical Equipment - Part 1: General Requirements for Safety
IEC 60601-1-2 2020 Ed 4.1	Medical Electrical Equipment - Part 1-2: Generalrequirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-3: Edition 2.2, 2021	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 2023e	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

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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)

9. Summary of Clinical Tests:

For the new detectors, X.fluoro and X.wi-D24, expert evaluations according to "*Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices*" have been conducted at the University Hospital Augsburg in Germany, Klinikum rechts der Isar Munich in Germany, Herz-Jesu-Krankenhaus Münster/Hiltrup in Germany and ZAS Jan Palfijn Hospital of Merksem in Belgium. The evaluation shows that the images are acceptable for diagnostic in radiography & fluoroscopy.

A US board-certified radiologist evaluated the detector X.fluoro (Pixium 4343F-5) in a clinical image quality evaluation. He evaluated multiple images and fluorography studies from different body regions. He determined that the images and fluorography studies with this detector were qualified for proper diagnosis.

10. 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 healthcare 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 LUMINOS Q.namix T and LUMINOS Q.namix R are substantially equivalent to the predicate devices, Luminos Agile Max and Luminos dRF Max. The LUMINOS Q.namix T/LUMINOS Q.namix R systems have similar indications for use that do not impact the overall intended use, the same fundamental scientific technology, and the same performance characteristics as the predicate devices. According to this submission material and the documentation provided, Siemens concludes that the LUMINOS Q.namix T and LUMINOS Q.namix R are substantially equivalent to the predicate devices.

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12. 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

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