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

April 2, 2018

Re: K173639
Trade/Device Name: Luminos Agile Max, Luminos dRF Max, Uroskop Omnia Max, Multitom Rax
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA
Dated: March 9, 2018
Received: March 13, 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Michael D. O'Hara For

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)*

K173639

Device Name
Luminos Agile Max

Indications for Use *(Describe)*

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.

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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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)*

Device Name
Luminos dRF Max

Indications for Use *(Describe)*
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.

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)

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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)*

Device Name
Multitom Rax

Indications for Use *(Describe)*
Multitom Rax 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.

Multitom Rax 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)

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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)*

Device Name
Uroskop Omnia Max

Indications for Use *(Describe)*

Uroskop Omnia Max is a device intended to visualize anatomical structures by converting an X-ray pattern into a visible image. The system is designed primarily for urological diagnosis and the support of urological therapeutic applications such as examinations and small interventions of the urogenital tract. The table supports endourological and minimal invasive surgery in urology as there are transurethral interventions (e.g. ureterorenoscopy (URS), double stent placement, cystoscopy, transurethral resection of bladder tumors (TURB), transurethral resection of the prostate (TURP)), percutaneous urological procedures (e.g. percutaneous nephrostomy (PCN), percutaneous nephrolitholapaxy (PCNL)), urological X-ray diagnosis (e.g. survey imaging of the kidney, ureter, and bladder (KUB), intravenous pyelogram (IVP), retrograde pyelography), micturition cystourethrogram (MCU), videourodynamics, laparoscopic procedures and minor open urological interventions. The system may be used on pediatric, adult and bariatric patients.

Uroskop Omnia 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)

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K173639 510(k) Summary: Software Update VF10 for Luminos Agile Max, Luminos dRF Max, Multitom Rax, Uroskop Omnia Max

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

Date Prepared: March 9, 2018

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
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:**
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Alternate Contact Person:
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Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
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Malvern, PA 19355
patricia.d.jones@siemens-healthineers.com

3. Device Names and Classifications:

Trade Names: Luminos Agile Max
Luminos dRF Max
Uroskop Omnia Max
Multitom Rax

Product Code: OWB

Secondary Product Code: JAA

Classification Names: System, x-ray, fluoroscopic, image-intensified, Interventional fluoroscopic x-ray system

Classification Panel: Radiology

Regulation: 21 CFR §892.1650

Device Class: II

4. Table 1: Legally Marketed Predicate Devices

Trade Name	**Luminos Agile**	**AXIOM Luminos dRF**	**Uroskop Omnia**	**Multitom Rax**
510(k) Number	K111292	K062623	K101491	K152928
Device Classification Name	System, x-ray, fluoroscopic, image-intensified	interventional fluoroscopic x-ray system	System, x-ray, fluoroscopic, image-intensified	interventional fluoroscopic x-ray system
Regulation Medical Specialty	Radiology	Radiology	Radiology	Radiology
Review Panel	Radiology	Radiology	Radiology	Radiology
Product Code	JAA	OWB	JAA	OWB
Subsequent Product Codes	IZI	JAA, OXO	MQB	JAA
Regulation Number	892.1650	892.1650	892.1650	892.1650
Device Class	2	2	2	2

5. Device Description:

All four radiology imaging devices are stationary X-ray systems for radiography and fluoroscopy. They use the same X-ray generator, the same X-ray tube and similar collimators. They also share the same imaging and system control device: The Fluorospot Compact. The reason for this submission is the upgrade of all systems to the software VF10. This new software will bring the following new features to the devices:

Table 2: New Features

Product Name	IEC 4th for EMC	Windows 10	Cyber-security package	Pediatric package	Use hospital IT (e.g. RIS) on modality	16 fps mode for 3D	SSXI update
Luminos Agile Max	√	√	√	√	√		√
Luminos dRF Max	√	√	√	√	√		√
Uroskop Omnia Max	√	√	√	√	√		√
Multitom Rax	√	√	√	√	√	√	√

The image processing algorithms (Diamond View Plus) will be used for exposures without grid and fluoroscopy image processing algorithms will be enhanced and called “Clearview”
Also the name suffix “Max” is being established as an addition to the product name of Luminos Agile, Luminos dRF and Uroskop Omnia.

6. Indications for Use:

The Indications for use have been revised for clarity and alignment.

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 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**.**

Multitom Rax 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

Multitom Rax is not for mammography examinations.

Uroskop Omnia Max is a device intended to visualize anatomical structures by converting an X-ray pattern into a visible image. The system is designed primarily for urological diagnosis and the support of urological therapeutic applications such as examinations and small interventions of the urogenital tract. The table supports endourological and minimal invasive surgery in urology as there are transurethral interventions (e.g. ureterorenoscopy (URS), double stent placement, cystoscopy, transurethral resection of bladder tumors (TURB), transurethral resection of the prostate (TURP)), percutaneous urological procedures (e.g. percutaneous nephrostomy (PCN), percutaneous nephrolitholapaxy (PCNL)), urological X-ray diagnosis (e.g. survey imaging of the kidney, ureter, and bladder (KUB), intravenous pyelogram (IVP), retrograde pyelography), micturition cystourethrogram (MCU), videourodynamics, laparoscopic procedures and minor open urological interventions. The system may be used on pediatric, adult and bariatric patients.

Uroskop Omnia Max is not for mammography examinations.

7. Substantial Equivalence:

The new system software VF10 does not alter the fundamental indication for use nor does it change the technology being used for X-ray imaging. The devices remain within the same classification regulation for the same indication for use as the predicate devices. The new system software design was completed in accordance with Siemens Quality Management System Design Controls comparable to the processes available for the predicate devices. 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 were the same or similar to the testing being used with the predicate devices.

The new system software VF10 controls solid state X-ray imagers (SSXI) similar to the imagers being used with the predicate devices. The SSXIs have been improved for mechanical robustness.

- *The edges of the mobile detectors were reinforced with steel caps to increase the mechanical robustness.*
- *The handle of the MAX wi-D will not be coated anymore with white film and will appear in a black carbon fiber look.*

The following tables compare the performance changes of the detectors being used with the VF10 to the predicate detectors. The changed data are highlighted in bold letters.

Table 3: Comparison of Detector 4343-F Subject and Predicate

	VE 20 / K152928	VF 10 K173639
Fluoroscopy detector	Pixium 4343-F	Pixium 4343-F
Field of view (Max)	42 cm x 42.6cm	42.0 cm x 42.**5** cm
Matrix size	Up to 2840 x 2874 pixel	Up to 2840 x 2874 pixel
DQE; 200 nGy	65 % at 0.05 lp/mm	65 % at 0.05 lp/mm
	51 % at 1 lp/mm	51 % at 1 lp/mm
	41 % at 2 lp/mm	41 % at 2 lp/mm
	25 % at 3 lp/mm	25 % at 3 lp/mm
	16 % at 3.4 lp/mm (Nyquist)	16 % at 3.4 lp/mm (Nyquist)
MTF	66 % at 1 lp/mm	66 % at 1 lp/mm
	35 % at 2 lp/mm	35 % at 2 lp/mm
	19 % at 3 lp/mm	19 % at 3 lp/mm
	16 % at 3.4 lp/mm (Nyquist)	1**5** % at 3.4 lp/mm (Nyquist)

Table 4: Comparison of Detector MAX wi-D Subject and Predicate

Mobil Rad detector	VE 20 / K152928	VF 10
Siemens Name	MAX wi-D	MAX wi-D
Trixell name	Pixium 3543 EZh	Pixium 3543 EZh
Dimensions	34.9 cm x 42.5 cm	34.**8** cm x 42.**4** cm
Matrix size	2356 x 2872	23**50** x 28**66**
DQE; 2 μ Gy	66 % at 0.05 lp/mm	**70** % at 0.05 lp/mm
	50 % at 1 lp/mm	5**1** % at 1 lp/mm
	40 % at 2 lp/mm	4**2** % at 2 lp/mm
	24 % at 3 lp/mm	2**9** % at 3 lp/mm
	17 % at Nyquist	1**9** % at Nyquist
MTF	61 % at 1 lp/mm	6**3** % at 1 lp/mm
	31 % at 2 lp/mm	3**5** % at 2 lp/mm
	15 % at 3 lp/mm	1**9** % at 3 lp/mm
	12 % at Nyquist	12 % at Nyquist

Table 5: Comparison of Detector MAX mini Subject and Predicate

Mobil Rad detector	VE 20 / K152928	VF 10
Siemens Name	MAX mini	MAX mini
Trixell name	Pixium 2430EZ	Pixium 2430EZ

Dimensions (active area)	28.4 cm x 22.8 cm	28.4 cm x 22.**5** cm
Matrix size	1920 x 1538	1920 x 152**0**
DQE; 2 μ Gy	66 % at 0.05 lp/mm	66 % at 0.05 lp/mm
	50 % at 1 lp/mm	50 % at 1 lp/mm
	40 % at 2 lp/mm	40 % at 2 lp/mm
	24 % at 3 lp/mm	24 % at 3 lp/mm
	17 % at Nyquist	17 % at Nyquist
MTF	61 % at 1 lp/mm	61 % at 1 lp/mm
	31 % at 2 lp/mm	31 % at 2 lp/mm
	15 % at 3 lp/mm	15 % at 3 lp/mm
	12 % at Nyquist	12 % at Nyquist

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

The subject devices with the new software VF10 use the same X-ray generator, the same X-ray tube and the similar SSXI with the same digital imaging system and similar image processing software as the predicate devices. There are no changes in the patient environment or the type of user interface.

The following table compares the main performance data of the subject devices with the predicate devices to substantiate equivalence of the subject device and predicate devices.

Table 6: Technical Comparison with the Predicates

	Subject Devices	**Predicate Devices**	
Feature	**Luminos Agile Max Luminos dRF Max Uroskop Omnia Max Multitom Rax**	**Luminos Agile AXIOM Luminos dRF Uroskop Omnia Multitom Rax**	**Comparison/ Comments**
X-ray			
Generator	Polydoros 65/80 kW	Polydoros 65/80 kW	X-ray Imaging components are the 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	
	Pulsed fluoroscopy	Pulsed fluoroscopy	
	DSA and series exposure	DSA and series exposure	

Organ programs	X-ray parameters Imaging processing parameters	X-ray parameters Imaging processing parameters	
Testing			
IEC Compliance for 60601-1-2 EMC	IEC 4th edition	IEC 3rd edition	Testing according to current IEC test scope
Digital Imaging			
Fluoroscopic SSXI integrated into system	Trixell Pixium 5100 Max Dynamic = 4343F-4	Trixell Pixium 5100 Max Dynamic = 4343F-3	Image Chain is similar to predicate devices. Detector Performance data according To SSXI guidance are provided
SSXI for Rad imaging	Trixell Pixium MAX wi-D = 3543EZh MAX mini = 2430EZ	Trixell Pixium MAX wi-D = 3543EZh MAX mini = 2430EZ	
Digital imaging system	Fluorospot Compact	Fluorospot Compact	
Image processing	Diamond View Plus Clearview	Diamond View Plus Application specific organ programs	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
Maximum Frame rate (acquisition)	16 Frames/second*	8 Frames/second	Improved dynamic resolution
*For Multitom Rax only			
Pediatric package	Increased number of organ programs	Organ programs	Increased number and variability

9. Summary of Non-Clinical Test Data:

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

Table 7: Compliance with Standards

The following international standards were used in the development of the VF10:

Development Organization and Reference Number	Standard Title
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
IEC 60601-2-43:2010 Edition 2.0	Medical electrical equipment - Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures

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. All radiology and fluoroscopy systems use the same software. Certain

features of the software are enabled or disabled depending on the system and its indications for use (i.e. 16 frames per second for Multitom Rax versus 8 frames per second for all other systems. 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 devices are safe and effective, perform comparably to the predicate devices, and are substantially equivalent to the predicate devices.

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 five devices comply with 21 CFR 1020.30-32 Federal Performance Standards for X-Ray Fluoroscopic 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
1020.32(d)	Fluoroscopic Entrance exposure rate
1020.32 (a)	Primary Protective Barrier Transmission
1020.31(a)	Peak Tube Potential
1020.32(b)	Alignment of edges of the X-ray field with the edges of the fluoroscopic image receptor
1020.32(k)	Display of values of AKR and cumulative air kerma
1040.10	Laser products

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".

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 devices the devices with the new software VF10 support a determination of substantial equivalence.

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 radiology and fluoroscopy devices with VF10 software are intended for the same indications for use as the predicate devices. The operating environment is the same and the technology is effectively unchanged. Siemens concludes via the documentation provided in this 510(k) submission that the radiology and fluoroscopy devices Luminos Agile Max, Luminos dRF Max, Uroskop Omnia Max and Multitom Rax with VF10 software are substantially equivalent to the predicate devices Luminos Agile, AXIOM Luminos dRF, Uroskop Omnia, Multitom Rax.

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