KARL STORZ Endoscopy America, Inc
% Mr. Mario Trujillo
Associate Regulatory Affairs Specialist
2151 E. Grand Avenue
EL SEGUNDO CA 90245

December 29, 2020.

Re: K200965
Trade/Device Name: XR-MX/1000
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: JAA
Dated: November 23, 2020
Received: November 27, 2020

Dear Mr. Trujillo:

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)*
K200965

Device Name

XR-MX/1000

Indications for Use *(Describe)*

The XR-MX/1000 system is a solid-state detector fluoroscopic X-ray system, primarily for urological applications (functional x-ray diagnostics, endourology and minimally invasive urological surgery). The system may be used for urological treatment, planning and diagnostic procedures, including but not limited to:

- Querying and retrieving patient information and/or image from other modalities[1]
- X-ray examinations of the urogenital area (e.g. cystoscopy, kidney, bladder, ureter, urethra) including KUB[2], IVP, reflux-cystogram, cystourethrogram, and micturition cystourethrogram combined with uroflow measurements.[3]
- Endourological interventions (e.g. of the urethra, prostate, bladder, sphincter, ostium, kidney and ureter, catheter placement, penile implant placement, transurethral resection of prostate or bladder, alternative treatment of the BPH and brachytherapy).[3]
- Percutaneous interventions (e.g. PCN nephrolithotomy, resection, percutaneous nephrostomy)[3]
- Application of fistula (kidney/bladder)[3]
- Simple procedures (e.g. urethra, testis, phimosis)[3]
- Intracorporeal shock wave lithotripsy[3]
- Uroflow/urodynamics[3]
- Pediatric radiological and therapeutic applications[3](ages 2 to 22 years)

[1] In conjunction with the StorM-Base 2.0 System (K093603)
[2] KUB Not indicated for XR-MX/1000 model FD21
[3] In conjunction with the Modulith SLX-F2 system (K072788)

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

K200965

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant:	KARL STORZ Endoscopy-America, Inc 2151 E. Grand Avenue EI Segundo, CA 90245
Contact:	Mario Trujillo Associate Regulatory Affairs Specialist 424-218-8184 (phone)
Date of Preparation:	November 23, 2020
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: XR-MX/1000 Classification Name: Image-intensified fluoroscopic X-ray system
Product Code:	JAA
Regulation:	21 CFR 892.1650 (Fluoroscopic, Image Intensified X-Ray System)
Predicate Device:	Uroview FD (K161019)
Device Description:	The operating principle of the subject devices, XR-MX/1000, manufactured by STORZ MEDICAL, AG., is identical to the predicate device, Uroview FD, manufactured by Pausch Medical GMBH, cleared via K161019. Both the subject and predicate devices include the following major X-ray components: • Basic unit (C-MX C-Arc) • X-Ray generator (source) • X-Ray tube and housing (column) • Collimator (image receptor) • Measuring chamber (image receptor) • Detector (image receptor) • Digital image station (image receptor) The basic unit of the subject devices is comprised of an arm that is shaped in the letter “C” which gives the component its name “C-arc”. One end of the C-arc includes an x-ray source and the opposite

	end includes an image receptor; while the basic unit of the predicate device is comprised of a urological table. The x-ray source emits the focused x-ray energy which is then transmitted through the body and is finally captured by the receptor, providing an image of the desired anatomy. The basic unit in both the subject and predicate devices is able to move, allowing the user to position the X-ray image chain at various angles and distances with respect to the patient anatomy being imaged. Additionally, the subject and predicate devices both include a workstation, which includes a monitor suspension arm that allows dual monitors for image display (radiologic and/or endoscopic) and space that allows other devices (e.g. camera control unit, documentation unit, etc.)
Intended Use and Indications for use:	The XR-MX/1000 system is a solid-state detector fluoroscopic X-ray system, primarily for urological applications (functional x-ray diagnostics, endourology and minimally invasive urological surgery). The system may be used for urological treatment, planning and diagnostic procedures, including but not limited to: • Querying and retrieving patient information and/or image from other modalities[1] • X-ray examinations of the urogenital area (e.g. cystoscopy, kidney, bladder, ureter, urethra) including KUB[2], IVP, reflux-cystogram, cystourethrogram, and micturition cystourethrogram combined with uroflow measurements.[3] • Endourological interventions (e.g. of the urethra, prostate, bladder, sphincter, ostium, kidney and ureter, catheter placement, penile implant placement, transurethral resection of prostate or bladder, alternative treatment of the BPH and brachytherapy).[3] • Percutaneous interventions (e.g. PCN nephrolithotomy, resection, percutaneous nephrostomy)[3] • Application of fistula (kidney/bladder)[3] • Simple procedures (e.g. urethra, testis, phimosis)3 • Intracorporeal shock wave lithotripsy[3] • Uroflow/urodynamics[3] • Pediatric radiological and therapeutic applications[3](ages 2 to 22 years) [1]In conjunction with the StorM-Base 2.0 System (K093603) [2]KUB Not indicated for XR-MX/1000 model FD21 [3]In conjunction with the Modulith SLX-F2 system (K072788)
Technological Characteristics:	The XR-MX/1000 systems are updated versions of the model XR-MX systems (K004037) as part of the continuous X-ray

	system evolution. Major X-ray components are similar to the predicate and new components use FDA-cleared or FDA-registered X-ray components. Thus, the subject devices are substantially equivalent, as the predicate device.
Non-Clinical Performance Data:	The XR-MX/1000 systems follow the FDA recognized consensus standards and is tested according to the following standards and FDA Guidance: • Electrical Safety and EMC o IEC 60601-1 o IEC 60601-1-2 o IEC 60601-1-3 o IEC 60601-1-6 o IEC 60601-2-28 o IEC 60601-2-54 • Software Verification and Validation Testing o Guidance for the Content of Premarket Submissions for Software Contained in Medical Device o Level of concern: Minor Additional bench testing was performed to ensure the device met its design specifications. The bench testing performed verified and validated that the XR-MX/1000 systems have met all their design specifications and are substantially equivalent to the predicate device.
Substantial Equivalence:	The intended use, operating principles, technological characteristics and features are similar, if not identical, between that subject and predicate devices. The minor differences between the subject and predicate devices that do not raise new or different questions or safety and effectiveness are: • The subject devices offer the standalone C-arc X-ray System whereas the predicate offers the urological table. • The subject devices use similar generators, X-ray tubes, measuring chambers, Collimators, Detectors and Digital Imaging Systems. As proven by the comparisons and rationale in this section, the above differences do not raise different questions of safety and effectiveness because the intended use, operating principles,

	technological characteristics, and features are significantly similar, if not identical. Both systems also comply with identical standards and safety testing, where applicable.
Clinical Performance Data:	Clinical performance is not required to demonstrate substantial equivalence to the predicate devices. Non-clinical bench testing was sufficient to establish substantial equivalence.
Conclusion:	The XR-MX/1000 systems are substantially equivalent to the predicate device. The non-clinical bench and comparative testing demonstrate that the device is as safe and effective as the legally marketed devices.