March 30, 2021

KARL STORZ Endoscopy-America, Inc.
Winkie Wong
Manager, Regulatory Affairs
2151 E. Grand Avenue
El Segundo, CA 90245

Re: K201001
Trade/Device Name: Modulith SLX-F2
Regulation Number: 21 CFR§ 876.5990
Regulation Name: Extracorporeal Shock Wave Lithotripter
Regulatory Class: II
Product Code: LNS
Dated: February 26, 2021
Received: March 2, 2021

Dear Winkie Wong:

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,

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201001

Device Name
Modulith SLX-F2

Indications for Use *(Describe)*

The STORZ MEDICAL Lithotripter Model MODULITH® SLX-F2 is indicated for the use in the noninvasive fragmentation of calculi in the kidney, in upper, middle and lower ureter for all adults and children 3 years or over.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) SUMMARY

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:	Winkie Wong Regulatory Affairs Manager 424-218-8379 (phone)
Date of Preparation:	April 22nd, 2020
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: MODULITH SLX-F2 Common Name: Lithotripter, Excorporeal Shock-Wave, Urological Classification Name: Extracorporeal shock wave lithotripter
Product Code:	LNS
Regulation:	21 CFR 876.5990
Predicate Device(s):	Modulith SLX-F2 180 (K072788) – Primary LM-9300 ELMA (K142561) - Secondary ***The above reference device have not been subject to any recall***
Device Description:	The MODULITH® Lithotripter SLX-F2 is an Extracorporeal Shock Wave Lithotripter Device. It generates shock waves that are focused onto the urinary calculi so that the stone fragments can be passed with the patient's urine.
Intended Use and Indications for use:	The STORZ MEDICAL Lithotripter Model MODULITH® SLX-F2 is indicated for the use in the noninvasive fragmentation of calculi in

	the kidney, in upper, middle and lower ureter for all adults and children 3 years or over.
Technological Characteristics:	The MODULITH SLX-F2 is a modification to the Modulith SLX-F2 180. The inclusion of pediatric patients as well as treatment of pancreatic, middle and lower ureter stones in its indication does not raise new or different issues of safety and effectiveness as supported by reviews of published literatures. Thus, the subject devices are substantially equivalent to the predicate device.

Non-Clinical
 	
Performance Data:
	The MODULITH SLX-F2 follows 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 60601-2-36
	  o IEC 61849
	• Software Verification and Validation Testing
	  o Guidance for the Content of Premarket Submissions for Software Contained in Medical Device
	  o Level of concern: Moderate
	
	Additional bench testing was performed to ensure the device met its design specifications. The bench testing performed verified and validated that the MODULITH SLX-F2 has met all its design specification and is substantially equivalent to its 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 do not raise new or different questions or safety and effectiveness. As proven by the comparisons and rationale in this section, the 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. However, literature reviews on the effectiveness of the subject device or equivalent devices on pediatric population and an analysis of stone composition in patient between 1 to 18 years old to support the applicability of OUS data to US population was provided to establish substantial equivalence for use in pediatric populations.
Conclusion:	The MODULITH SLX-F2 is substantially equivalent to its predicate device. The non-clinical bench, literature review and comparative testing demonstrate that the device is as safe and effective as the legally marketed devices.