January 10, 2018

E.M.S. Electro Medical Systems SA
% Sheila Hemeon-Heyer
President
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, MA 01002

Re: K173234
Trade/Device Name: Swiss LithoClast Trilogy
Regulation Number: 21 CFR§ 876.4480
Regulation Name: Electrohydraulic Lithotripter
Regulatory Class: II
Product Code: FEO, FFK
Dated: October 4, 2017
Received: October 5, 2017

Dear Sheila Hemeon-Heyer:

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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*
K173234

Device Name

Swiss LithoClast Trilogy

Indications for Use *(Describe)*

The Swiss LithoClast Trilogy is indicated for fragmentation and removal of urinary tract calculi in the kidney, ureter, and bladder.

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 per the requirements of 21 CFR 807.92.

A. 510(k) Applicant:

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B. Date Prepared: January 9, 2018

D. Device Name and Classification Information:

Trade Name:	Swiss LithoClast® Trilogy
Classification Name:	Electrohydraulic Lithotripter
Regulation:	21 CFR 876.4480
Product Code:	FEO, FFK
Review Panel:	78 Gastroenterology / Urology
Class:	II

E. Predicate Device(s): K012445, Swiss LithoClast® Master

F. Summary Device Description:

The Swiss LithoClast® Trilogy is a modified version of the Swiss LithoClast® Master, previously cleared under K012445. As with the predicate device, three possible modes of operation are available: 1) pneumatic lithotripsy alone; 2) ultrasound lithotripsy alone; and 3) and combined pneumatic and ultrasound lithotripsy.

The LithoClast Trilogy system consists of the console used to set the treatment parameters and generate the treatment energy, a reusable handpiece, and a variety of probe sizes to enable use of the system with a wide range of commercially available endoscopes. Delivery of energy is controlled using a two-step foot pedal.

Two models of the LithoClast Trilogy are available: one with a peristaltic pump and one with a pinch valve. Both versions can be used to suction stone fragments into the optional Stone Catcher. An external vacuum system is required to enable suction with the pinch valve model of the console.

510(k) Summary

G. Intended Use / Indication for Use:

The Swiss LithoClast® Trilogy is indicated for fragmentation and removal of urinary tract calculi in the kidney, ureter, and bladder.

H. Technical Comparison with Predicate Device

The table below provides a side-by-side comparison of the modified device to the predicate device.

Characteristic	Ems Swiss Lithoclast Master (K012445)	Ems Swiss Lithoclast Trilogy	Basis for SE
Indications for use	Fragmentation of urinary tract calculi in the kidney, ureter and bladder	Fragmentation and removal of urinary tract calculi in the kidney, ureter and bladder	Substantially equivalent
DEVICE COMPONENTS			
CONSOLE			
Microprocessor control	Yes	Yes	Same
I/O	Rotary knobs/switches LCD display	Touchscreen input LCD display	Substantially equivalent
Dimensions	135 mm (H) x 371 mm (W) x 432 mm (D	135 mm (H) x 360 mm (W) x 420 mm (D)	Substantially equivalent
Weight	10.5 kg	13.5 kg	Substantially equivalent
Power supply	100-240 VAC, 50-60 Hz	100-240 VAC, 50-60 Hz	Same
HANDPIECE			
Handpiece types	Separate handpieces for ultrasound and pneumatic	Single handpiece	Single handpiece delivers both energy types
Handpiece housing material	PEEK	PEEK	Same
Sterilization	Re-usable, pre-vacuum, steam	Re-usable, pre-vacuum, steam	Same
PROBES			
Probe types	Separate probes for ultrasound (vibration) and ballistic (shock wave)	Single probe provides both ultrasound (vibration) and ballistic (shock wave)	Single probe delivers both energy types
Probe material	Ultrasound: 316L stainless steel Ballistic: 304 stainless steel	Ultrasound: 316L stainless steel	Same as for ultrasound probe

510(k) Summary

Characteristic	Ems Swiss Lithoclast Master (K012445)	Ems Swiss Lithoclast Trilogy	Basis for SE
Probe diameters	Pneumatic: 0.8, 1.0, 1.6, 2.0 and 3.2 mm Ultrasound: 3.3 and 3.8 mm	1.1, 1.5, 1.9, 3.4 and 3.9 mm	Equivalent range
RFID tag	None	Yes	Enables console to track probe type and use history
Sterilization	Provided EtO sterilized, Multiple-use probes validated for 4x steam sterilization after first use	Provided EtO sterilized, Multiple-use probes validated for 4x steam sterilization after first use	Same
FOOT PEDAL	Dual side-by-side Two-step for suction and ultrasound	Single pedal Two-step for suction and energy	Only one pedal needed due to integrated energy
SUCTION	Pinch valve on console, compatible with EMS LithoVac	Options of pinch valve or peristaltic pump on console	Substantially equivalent
STONE CATCHER	Optional component	Optional component	Same product
OPERATING MODES			
ULTRASOUND MODE	Yes	Yes	Same
Transducer frequency	24 kHz	24 Hz	Same
Max. amplitude Peak to peak	60 µm	60 µm	Same
Output power adjustment	Adjustable from 0%-100% (10% increments)	Adjustable from 10%-100% (10% increments)	Substantially equivalent
BALLISTIC MODE	Yes	Yes	Same
Energy Type	Ballistic, generated by compressed air	Ballistic, generated by electromagnetic field	Different energy source
Output power adjustment	Adjustable from 0%-100% (10% increments)	Adjustable from 10%-100% (10% increments)	Substantially equivalent
Operating modes	Single shot or multiple shot modes	Multiple shot mode only	Single shot mode eliminated as rarely used
Multiple shot repetition rate	1 to 12 Hz in 1 Hz increments	1 to 12 Hz in 1 Hz increments	Same

510(k) Summary

I. Basis for Substantial Equivalence – Bench Testing

The following FDA guidance documents were followed for this 510(k):

- "Guidance for the Content of Premarket Notifications for Intracorporeal Lithotripters," Nov. 30, 1998
- "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," May 11, 2005
- "Off-The-Shelf Software Use in Medical Devices," Sept. 9, 1999
- "Radio Frequency Wireless Technology in Medical Devices," August 14, 2013
- "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" June 16, 2016
- "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile," January 21, 2016

Testing submitted in this 510(k) to support substantial equivalence included the following:

- Fragmentation and stone clearance time using the dual energy Trilogy handpiece and probes and artificial Begostones
- Tissue perforation testing on pig bladder tissue
- Reusable handpiece qualification testing
- Reusable probe qualification testing
- Electrical safety testing to IEC 60601-1:2005 +A1:2012 (ed. 3.1)
- Electromagnetic compatibility testing to IEC 60601-1-2:2014 (ed. 4.0)
- Biocompatibility testing to ISO 10993-1 including:
    - Cytotoxicity: ISO 10993-5:2009
    - Sensitization: ISO 10993-10:2010
    - Intracutaneous reactivity in rabbits: ISO 10993-10:2010
    - Acute Systemic Toxicity in Mice: ISO 10993-11:2006
    - Endotoxin (LAL) test: USP39 <85> 2016, USP39 <161> 2016
    - Material-mediated Pyrogenicity: ISO 10993-11:2006, USP <151> Pyrogen Test
- Sterilization validation to ISO 11135:2014
- Shipping and handling testing to ISTA 1E and ISTA 2A
- Package and sterility testing after 2X EtO sterilization and accelerated aging including:
    - Visual inspection to ASTM F1886:2016
    - Seal peel and seal tensile strength tests to EN 868-5:2009
    - Seal integrity test to ASTM F1929:2015
    - Dye penetration test for pinholes to EN 868-5:2009

    - Sterility tests to ISO 11737-2:2009
- Functional tests of the Trilogy probes after aging
- Software verification and validation to IEC 62304:2006

J. Conclusion

The information and testing presented in this 510(k) demonstrate that the modified Swiss LithoClast device, called the Trilogy, is substantially equivalent to the predicate Swiss LithoClast device, called the Master. The modified device has the same intended use, equivalent indications for use, and same fundamental scientific technology as compared to the predicate device. The test data submitted in the 510(k) demonstrate that the modified device is as safe and as effective as the predicate device and, therefore, can be found substantially equivalent.