August 30, 2018

EMS Electro Medical Systems SA
% Sheila Hemeon-Heyer, JD, RAC
President
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, MA 01002

Re: K181997
Trade/Device Name: Swiss LithoClast Trilogy
Regulation Number: 21 CFR§ 876.4480
Regulation Name: Electrohydraulic Lithotripter
Regulatory Class: II
Product Code: FEO, FFK
Dated: July 30, 2018
Received: August 1, 2018

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

for
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)*
K181997

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Special 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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c/o Sonia Callegaro
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B. Date Prepared: July 24, 2018

D. Device Name and Classification Information:

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

E. Predicate Device(s): Swiss LithoClast® Trilogy, K181364

F. Summary Device Description:

The Swiss LithoClast® Trilogy is an intracorporal lithotripter with three possible modes of operation: 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.

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

This Special 510(k) is submitted to describe an engineering modification to improve the durability of the reusable handpiece. There have been no changes to the indications for use, principles of operation, or technological specifications of the Swiss LithoClast® Trilogy system.

I. Basis for Substantial Equivalence

Substantial equivalence of the engineering change to the Trilogy handpiece was demonstrated by validation of the change in accordance with the EMS risk management and design change control procedures. Summaries of the risk analysis and validation testing were provided in this 510(k). No new risks or change in the device risk level were identified. The revised handpiece met the acceptance criteria of the validation testing.

J. Conclusion

The information and testing presented in this 510(k) demonstrate that the modified Swiss Lithoclast® Trilogy system is substantially equivalent to the predicate Swiss Lithoclast® Trilogy system.