



October 23, 2023

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

Re: K230893  
Trade/Device Name: Swiss LithoClast® Trilogy  
Regulation Number: 21 CFR§ 876.4480  
Regulation Name: Electrohydraulic Lithotripter  
Regulatory Class: II  
Product Code: FEO, FFK  
Dated: September 21, 2023  
Received: September 21, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Mark J. Antonino -S**

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

## Indications for Use

510(k) Number (if known)  
K230893

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.

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### Traditional 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:** EMS Electro Medical Systems SA  
Ch. De la Vuarpillière 31  
1260 Nyon, Switzerland  
c/o Timothée Deblock  
Head of Quality  
T: +41 22 994 8516  
Email: tdeblock@ems-ch.com
- B. Date Prepared:** March 31, 2023
- 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: K191124
- F. Summary Device Description:**

The Swiss LithoClast® Trilogy offers three modes of lithotripsy: 1) ultrasound alone; 2) shock wave alone; or 3) combined ultrasound and shock wave.. The LithoClast Trilogy system consists of the console used to set the treatment parameters and generate the treatment energy, a dual-energy 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. The purpose of this 510(k) is to increased the number of validated reprocessing cycles for the reusable handpiece and add the option of a wireless foot pedal.

**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 Swiss LithoClast® Trilogy described in this 510(k) has the same indications for use and same technical characteristics as the predicate device. The purpose of this 510(k) is to add the option of a wireless foot pedal. This is the only change to the predicate Swiss LithoClast Trilogy device.

The table below provides a side-by-side comparison of the new and predicate devices. A more detailed discussion of the differences is provided following the table.

<b>Characteristic</b>	<b>Predicate Swiss LithoClast Trilogy (K191124)</b>	<b>Proposed Swiss LithoClast Trilogy</b>	<b>Basis for SE</b>
Manufacturer	EMS Medical Systems S.A.	EMS Medical Systems S.A.	Same
Indications for use	Fragmentation and removal of urinary tract calculi in the kidney, ureter and bladder	Fragmentation and removal of urinary tract calculi in the kidney, ureter and bladder	Same
<b>DEVICE COMPONENTS</b>			
<b>CONSOLE</b>			
Microprocessor control	Yes	Yes	Same
I/O	Touchscreen input LCD display	Touchscreen input LCD display	Same
Dimensions	172 mm (H) x 402 mm (W) x 451 mm (D)	172 mm (H) x 402 mm (W) x 451 mm (D)	Same
Weight	13.5 kg	13.5 kg	Same
Power supply	100-240 VAC, 50-60 Hz	100-240 VAC, 50-60 Hz	Same
<b>HANDPIECE</b>			
Handpiece types	Single handpiece	Single handpiece	Same
Handpiece housing material	PEEK	PEEK	Same
Sterilization	H2O2 or steam sterilization Steri Holder provided to position handpiece during steam sterilization	H2O2 or steam sterilization Steri Holder provided to position handpiece during steam sterilization	Same
# Reprocessing cycles	Up to 60	Up to 100	Different
<b>PROBES</b>			
Probe types	Single probe provides both ultrasound (vibration) and ballistic (shock wave)	Single probe provides both ultrasound (vibration) and ballistic (shock wave)	Same

Section 7: 510(k) Summary

Characteristic	Predicate Swiss LithoClast Trilogy (K191124)	Proposed Swiss LithoClast Trilogy	Basis for SE
Probe material	Ultrasound: 316L stainless steel	Ultrasound: 316L stainless steel	Same
Probe diameters	1.1, 1.5, 1.9, 3.4 and 3.9 mm	1.1, 1.5, 1.9, 3.4 and 3.9 mm	Same
RFID tag	Yes	Yes	Same
Sterilization	Provided EtO sterilized,	Provided EtO sterilized,	Same
# Reprocessing cycles	Multiple-use probes validated for 4x steam sterilization after first use	Multiple-use probes validated for 4x steam sterilization after first use	Same
<b>FOOT PEDAL</b>	Single pedal, wired Two-step for suction and energy	Single pedal, wired or wireless Two-step for suction and energy	Different
<b>SUCTION</b>	Options of pinch valve or peristaltic pump on console	Options of pinch valve or peristaltic pump on console	Same
<b>STONE CATCHER</b>	Optional component	Optional component	Same
<b>STERI HOLDER</b>	Provided for positioning of Trilogy handpiece during steam sterilization	Provided for positioning of Trilogy handpiece during steam sterilization	Same
<b>OPERATING MODES</b>			
<b>ULTRASOUND MODE</b>	Yes	Yes	Same
Transducer frequency	Around 24 kHz	Around 24 kHz	Same
Max. amplitude Peak to peak	60 µm	60 µm	Same
Output power adjustment	Adjustable from 10%-100% (10% increments)	Adjustable from 10%-100% (10% increments)	Same
<b>BALLISTIC MODE</b>	Yes	Yes	Same
Energy Type	Ballistic, generated by electromagnetic field	Ballistic, generated by electromagnetic field	Same
Output power adjustment	Adjustable from 10%-100% (10% increments)	Adjustable from 10%-100% (10% increments)	Same
Operating modes	Multiple shot mode only	Multiple shot mode only	Same
Multiple shot repetition rate	1 to 12 Hz in 1 Hz increments	1 to 12 Hz in 1 Hz increments	Same

The only differences shown in the above table are:

1. an RF wireless foot pedal has been added as an option to the wired foot pedal; and
2. the validated number of reprocessing cycles for the reusable handpiece has been increased from 60 to 100.

The foot pedal (wired or wireless) is used to control delivery of the shock waves through the handpiece. The wireless foot pedal is operated by the user in the same way as the previously cleared wired foot pedal. Testing submitted in this 510(k) (summarized below) demonstrates that these two changes do not raise any new or different questions of safety or effectiveness compared to the prior version of the Swiss LithoClast Trilogy cleared under K191124.

## **I. Basis for Substantial Equivalence**

The following categories of tests were conducted to provide performance data to support the substantial equivalence of the Swiss LithoClast Trilogy device with the proposed changes:

### Software Validation

The wireless foot pedal is used to control the delivery of energy from a medical device that has a moderate level of concern. Therefore, the software in the wireless foot pedal and dongle is also considered to have a moderate level of concern. This 510(k) included software documentation commensurate with a moderate level of concern and compliant with IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes. The software was validated in at the unit, integration, and system levels (i.e., with the software integrated into the final device). All tests met the acceptance criteria and were passed.

### Electrical Safety and EMC

The Swiss LithoClast Trilogy, operated by the wireless foot pedal, was tested and demonstrated to comply with the following standards:

- IEC 60601-1:2005 + A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

In addition, the Wireless Foot Pedal Kit was tested and demonstrated to comply with the following standards related to radiofrequency devices and RF wireless transmissions:

- EN 300 328 V2.2.2 (2019-07) Wideband Transmission Systems. Data Transmission Equipment Operating in the 24 GHz Band; Harmonised Standard for Access to Radio Spectrum
- EN 62311:2008 Assessment of Electronic and Electrical Equipment Related to Human Exposure Restriction for Electromagnetic Fields (0 Hz to 300 GHz)

#### Device Performance Testing

Comprehensive testing was conducted to confirm that the performance of the wireless foot pedal and dongle meet the design inputs requirements. These tests were done to internal protocols and covered the following requirements:

- Functional performance
- Battery performance
- Mechanical integrity testing
- Dongle connection / disconnection integrity
- Chemical resistance testing to cleaning and disinfection solutions
- Expected use lifetime testing
- RF quality of service and coexistence testing

All test results demonstrated that the wireless foot pedal and dongle meet the design input requirements.

#### Handpiece Lifetime Testing

Twenty handpiece units were subjected to 133 cleaning, disinfection, and steam sterilization cycles. Performance testing conducted after completion of these reprocessing cycles confirmed that the handpieces met the performance specifications and were effective in clearing stones in a simulated use set-up within 20% of the time needed using handpieces at time 0 (prior to the 133 reprocessing cycles), which met the test acceptance criteria. The conclusion of the testing was that the Swiss LithoClast Trilogy handpiece is validated for 100 reprocessing cycles with 95% reliability and 95% confidence.

### **J. Conclusion**

The information presented in this 510(k) demonstrate that the Swiss Lithoclast® Trilogy incorporating the changes as described is substantially equivalent to the Swiss Lithoclast® Trilogy as cleared under K191124.