August 13, 2025

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

Re: K243279
Trade/Device Name: DOLORCLAST Focused Shock Waves
Regulation Number: 21 CFR 878.4685
Regulation Name: Extracorporeal Shock Wave Device For Treatment Of Chronic Wounds
Regulatory Class: Class II
Product Code: PZL
Dated: July 22, 2025
Received: July 22, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JAMES H. JANG -S

Digitally signed by JAMES H. JANG -S
Date: 2025.08.13 09:29:05 -04'00'

James Jang, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243279

Device Name

DOLORCLAST Focused Shock Waves

Indications for Use *(Describe)*

The DOLORCLAST Focused Shock Waves System is intended to provide acoustic pressure shockwaves in the treatment of chronic, full-thickness diabetic foot ulcers with wound areas measuring no larger than 16 cm2, which extend through the epidermis, dermis, tendon, or capsule, but without bone exposure. The DOLORCLAST Focused Shock Waves system is indicated for adult (22 years and older), diabetic patients presenting with diabetic foot ulcers greater than 30 days in duration and is indicated for use in conjunction with standard diabetic ulcer care.

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 21 CFR 807.92.

A. Submitter:

E.M.S. Electro Medical Systems S.A.
Ch. de la Vuarpillière 31
1260 Nyon, Switzerland
Contact: Vivian Yee
Phone: +41 22 99 44 700
Email: vyee@ems-ch.com

B. Date Prepared: August 12, 2025

C. Device Name and Classification Information:

Trade name:	DOLORCLAST Focused Shock Waves
Regulation Name	Extracorporeal shock wave device for treatment of chronic wounds.
Review Panel	General & Plastic Surgery
Classification regulation:	21 CFR 878.4685
Product code:	PZL
Class:	Class II

D. Predicate Device(s):

Predicate Device: K202112, DUOLITH SD1 T-Top & Tower System with C-ACTOR Sepia Handpiece by Storz Medical AG

Reference: K191961, OrthoGold 100™ by Tissue Regeneration Technologies, LLC

E. Device Description:

The DOLORCLAST Focused Shock Waves system is composed of the DolorClast console, a handpiece, interchangeable gel pads (3 different sizes) and optional cart. EMS DolorClast Gel, previously approved under P050004 and K220538, is also provided for transmitting shock waves between the piezoceramic elements to the gel pad and coupling the treatment gel pad to the patient's skin.

The DOLORCLAST Focused Shock Waves system generates acoustic pressure waves generated using piezoelectric technology. A high-voltage impulse, controlled by the console, is used to stimulate the piezoceramic elements arranged across a concave surface in the emission source (the handpiece), causing the elements to expand simultaneously and briefly by a few micrometers, thus generating a focused shock wave. The shock waves are delivered to the patient's body via the handpiece, through a gel pad in a focused manner, and the treatment depth varies in line with the gel pad used.

F. Indications for Use Statement

The DOLORCLAST Focused Shock Waves System is intended to provide acoustic pressure shockwaves in the treatment of chronic, full-thickness diabetic foot ulcers with wound areas measuring no larger than 16 cm2, which extend through the epidermis, dermis, tendon, or capsule, but without bone exposure. The DOLORCLAST Focused Shock Waves system is indicated for adult (22 years and older) diabetic patients presenting with diabetic foot ulcers greater than 30 days in duration and is indicated for use in conjunction with standard diabetic ulcer care.

G. Comparison with Predicate Devices

Parameter	Proposed Device	Primary Predicate Device (K202112)
Device Trade Name	DOLORCLAST Focused Shock Waves	DUOLITH SD1 w/ C-ACTOR
Device Manufacturer	E.M.S. Electro Medical Systems S.A.	Storz Medical AG
Regulation	21 CFR 878.4685	21 CFR 878.4685
Product Code	PZL	PZL
Device Class	II	II
Indications for Use Statement	To provide acoustic pressure shockwaves in the treatment of chronic, full-thickness diabetic foot ulcers with wound areas measuring no larger than 16 cm2, which extend through the epidermis, dermis, tendon, or capsule, but without bone exposure. Indicated for adult (22 years and older) diabetic patients presenting with diabetic foot ulcers greater than 30 days in duration and is indicated for use in conjunction with standard diabetic ulcer care.	To provide acoustic pressure shockwaves in the treatment of chronic, full-thickness diabetic foot ulcers with wound areas measuring no larger than 16 cm2, which extend through the epidermis, dermis, tendon, or capsule, but without bone exposure. Indicated for adult (22 years and older), diabetic patients presenting with diabetic foot ulcers greater than 30 days in duration and is indicated for use in conjunction with standard diabetic ulcer care.
Modes of action	Focused pressure pulses	Focused pressure pulses
Mechanism of action	Extracorporeally induced pressure pulses	Extracorporeally induced pressure pulses
Operating mode	Continuous	Continuous
Electrical protection	Class I, B	Class I, B
User Interface	Touch Screen	Touch Screen
Firmware controlled	Yes	Yes
Type of Energy	Pressure pulses	Pressure pulses
Energy Source	100–127/220–240 VAC, 50-60Hz	100 – 240 V AC, 50–60 Hz
Type of Pressure/Shock Wave Generation	Piezoelectric, pressure wave caused by discharge of high voltage condensers	Electromagnetic, pressure wave under water caused by discharge of high voltage condensers
Operator selection of parameters (Intensity, Frequency,# of Pulses)	Yes	Yes

Parameter	Proposed Device	Primary Predicate Device (K202112)
Intensity Settings and corresponding ranges of Energy Flux Density (Total EFD)	0.1-20 (0.03–0.97 mJ/mm²)	No discrete settings or step increments stated (0.03 - 1.24 mJ/mm2)
Diameter of treatment applicator head	99 mm	62 mm
Number of applicator head offsets	Two	Two
Depth of applicator head offsets*	15mm: Gel Pad M (A) 30mm: Gel Pad S (B)	15 mm: Short Standoff (A) 30 mm: Long Standoff (B)
Therapeutically effective penetration depth (5 MPa) at maximum intensity setting: - No offset - Offset A - Offset B	 - 65 mm - 50 mm - 35 mm	 - 65 mm - 45 mm - 30 mm
Depth of focus: - No offset - Offset A - Offset B	 - 40 mm - 25 mm - 10 mm	 - 30 mm - 15 mm - 0 mm
Depth of focal zone - No offset - Offset A - Offset B	 - 30 - 50 mm - 15 - 35 mm - 0 - 20 mm	 - 20 - 40 mm - 0 - 20 mm - 0 - 10 mm
Pulse repeat rate (l/s) (min – max)	1 - 8 Hz	1 - 8 Hz
Number of pulses per treatment (min - max)	100-4,000	100-4,000**
System Dimensions (W x H x D)	340x 180 x 450 (console)	454 x 187 x 460 mm
Operating temperature	10 °C - 35 °C	10˚C - 30˚C
Operating Relative Humidity	Maximum 85%	5-55%
Treatment Duration (Typical)	5-15 min	10-20 min

*The offsets are called Gel Pads in the DOLORCLAST Focused Shock Waves system and are called Standoffs in the Duolith SD1 with C-Actor Handpiece system. For the DOLORCLAST Focused, the no offset (i.e., flat) treatment scenario is achieved using the D (i.e., deep penetration) gel pad, offset A is achieved using the M gel pad (i.e., medium penetration), and offset B is achieved using the S (i.e., shallow penetration) gel pad. For the Duolith SD1 C-Actor handpiece, the no offset treatment scenario (deep penetration) is achieved with the bare treatment head (no standoff), offset A is achieved using the Short (S) standoff (for medium penetration) and offset B is achieved using the Long (L) standoff (for shallow penetration).

**Based on Duolith US instruction manual the maximum impulses per treatment session available with the device is up to 4000. As with any ESWT system, the operator can always treat longer during a session by restarting the treatment.

H. Performance Testing

The following testing was included in this 510(k) to demonstrate the safety and effectiveness of the device and is substantially equivalent to the predicate devices:

Acoustic Pulse Characterization

The purpose of this study was to characterize the pressure field output of the DOLORCLAST Focused Shock Waves device. The method used was based on IEC 61846 Ultrasonics – Pressure pulse lithotripters – Characteristics of fields – First edition – 1998 and IEC 63045 - Ultrasonics – Non-focusing short pressure pulse sources including ballistic pressure pulse sources – Characteristics of fields – Edition 1.0 – 2020-05, The measurement method used a hydrophone to record pressure data generated by the device at different positions of the sensor relative to the focal point when set to different intensity levels from minimum to maximum. Both temporal and spatial measurements were recorded. The results were compared to publicly available information on the pressure pulse output of the Duolith SD1 with C-Actor Handpiece to demonstrate the substantial equivalence of the proposed and primary predicate devices.

System functional performance testing

- The operation of the DOLORCLAST Focused Shock Waves console was tested under an internal EMS protocol to confirm correct operation of the console at all treatment settings. All tests were passed.
- The operation of the DOLORCLAST Focus handpiece was tested under an internal EMS protocol to confirm correct operation of the handpiece including adjustment of the intensity, starting and stopping treatment. All tests were passed.

Lifetime Testing

Testing was conducted under internal EMS protocols to confirm that the DOLORCLAST Focused Shock waves console and handpiece continued to function and meet their performance specifications for the claimed useful lifetimes of:

- Console: 7 years
- Handpiece: 2 years or 5,000,000 pulses

Software Validation

The DOLORCLAST Focused Shock Waves system software was validated in both software testing and system level testing with the software integrated into the final device. Software development and testing was compliant with IEC 62304 Edition 1.1:2015-06 Medical device software – Software life-cycle processes.

Electrical Safety and EMC

The device 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

Biocompatibility Testing

The device labeling requires that the diabetic foot ulcer be covered with one of the recommended sterile wound dressings and contact gel throughout the treatment duration. Testing confirmed that the OpSite™ Wound Dressing (K852211 and K895408) and 3M Tegaderm™ +Pad (K811291 and K812678) are able to withstand worst case treatment conditions using the DOLORCLAST Focused Shock Waves without compromising their integrity. In addition, testing confirmed that the patient contacting materials of the DOLORCLAST Focused Shock Waves are biocompatible per the following ISO 10993 test standards for a surface device in contact with breached or compromised skin for prolonged duration (>24 h to 30 d, due to repeat treatment sessions):

- ISO 10993-1:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021 Biological evaluation of medical devices Part 10: Tests for skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices Part 11: Tests for systemic toxicity (Acute Systemic Toxicity and Material Mediated Pyrogenicity)
- ISO 10993-23:2021 Biological evaluation of medical devices Part 23: Tests for irritation

I. Conclusion

The information presented in this 510(k) demonstrates that DOLORCLAST Focused Shock Waves system is substantially equivalent to the predicate device under 21 CFR 878.4685, Product Code PZL for the treatment of diabetic foot ulcers.