July 2, 2025

Curative Sound Therapeutics
Les Bogdanowicz
Quality Manager
11611 N. Meridian Street
Suite 425
Carmel, Indiana 46032

Re: K250779
Trade/Device Name: CS-Pro MED
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: March 13, 2025
Received: March 14, 2025

Dear Les Bogdanowicz:

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: 2025.07.02 23:17:12 -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.

Submission Number *(if known)*

K250779

Device Name

CS-Pro MED

Indications for Use *(Describe)*

The CS-Pro MED is intended to provide acoustic shock waves 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 CS-Pro MED is indicated for adults (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.

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

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510(k) Summary

Sponsor

Curative Sound, LLC
11611 N. Meridian
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Carmel, IN 46032

Contact

Les Bogdanowicz PhD, MBA
VP of Quality and Regulatory Affairs
Ph: 224.585.3870
Les.Bogdanowicz@curative-sound.com

Date of Submission:	February 28, 2025
Proposed Class:	Class II
Proprietary Name:	CS-Pro MED
Regulation Name:	Extracorporeal Shock Wave Device for Treatment of Chronic Wounds
Classification Panel:	General and Plastic Surgery Devices
Regulatory Number:	21 CFR 878.4685
Product Code:	PZL

Predicate Devices

Equivalence is claimed to the predicate device: DuoLith SD1 with C-ACTOR (K202112).

Device Description

The CS-Pro MED is a handheld, battery-operated device that produces high-pressure, focused, acoustic shock waves. It is designed to provide healthcare professionals with an effective and easy-to-use device for administering focused Extracorporeal Shock Wave Therapy (ESWT) treatment. The CS-Pro MED is battery-powered and utilizes an array of piezocomposite transducers to create acoustic shock waves. The device delivers a drive signal to the piezocomposite transducers creating pressure pulses that propagate through the elastomeric standoffs and into the patient's tissue. Each pressure pulse is calibrated to arrive simultaneously at the focal point. The device includes a touch-sensitive display that indicates useful information and allows the operator to adjust the energy level, set the number of shock wave pulses, and adjust the pulse repetition frequency. The CS-Pro MED includes five standoffs of varying sizes to control the depth at which the therapy is focused, allowing the physician to target a specific tissue depth based on the treatment protocol.

Indications for Use

The CS-Pro MED is intended to provide acoustic shock waves 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 CS-Pro MED is indicated for adults (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.

Performance Data

The Curative Sound CS-Pro MED device complies with voluntary standards for electrical safety, electromagnetic compatibility, biocompatibility and characterization of pressure pulses. The following performance data are provided in support of the substantial equivalence determination:

Electrical Safety

- Electrical Safety testing in accordance with IEC 60601-1:2005/A1:2012 + A2:2020 (Edition 3.2), Medical Electrical Equipment – Part 1: General requirements for Basic Safety and Essential Performance
- Electrical Safety testing in accordance with ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, Medical Electrical Equipment – Part 1: General requirements for Basic Safety and Essential Performance Electromagnetic Compatibility
- Electrical Safety testing in accordance with IEC 60601-2-36 Edition 2.0: 2014-04, Medical electrical equipment - Part 2-36: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy

Electromagnetic Compatibility

- Electromagnetic compatibility testing in accordance with IEC 60601-1-2:2014/A1:2020 (Edition 4.1), Medical electrical equipment – Part 1-2: General requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances - Requirements and Tests

Risk Management

- Risk analysis in accordance with ISO 14971:2019 (Third Edition), Medical Device – Application of Risk Management to Medical Devices
- Hazard Analysis / Risk Management was performed and demonstrated that all risks are mitigated to an acceptable level

Biocompatibility

- There are no direct body patient contacting components since the CS-Pro MED standoff is separated from direct patient contact by a sterile barrier during treatment. Nevertheless, the treatment applicator head (standoff) component was tested to and meets applicable biocompatibility requirements.
- Biocompatibility evaluation was completed according to the FDA guidance document "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," dated September 04, 2020

Bench Testing

- Characterization of acoustic was performed per Per IEC 61846:1998, *"Therapeutic focused short pressure pulse sources – Characteristics of fields"*
- Nonclinical verification and validation testing was performed and demonstrated that the CS-Pro MED meets the design specifications and is safe and effective for its intended use. All tests required by the verification and validation plan were completed and passed. The testing demonstrates that the CS-Pro MED is substantially equivalent to the predicate devices.

Clinical Information

Not applicable. Bench and performance testing support the conclusion of substantial equivalence in this submission.

Technological Characteristics and Substantial Equivalence

The mechanism of action and technological characteristics of the CS-Pro MED and the predicate device are described in the comparison table below. Any differences between subject and predicate device do not raise any new questions of safety or effectiveness.

The CS-Pro MED generates extracorporeally induced acoustic shock waves to stimulate a biological healing response in treated tissue. The CS-Pro MED utilizes an array of piezoelectric transducers driven by an electrical signal to generate the acoustic shock waves.

Substantial Equivalence Comparison Table

Product Characteristic	Subject Device CS-Pro MED	DuoLith SD1 with C-ACTOR	Comparison
510(k) Number	To be assigned	K202112	
Indication of Use	Indicated to provide acoustic pressure shock waves in the treatment of chronic, full-thickness diabetic foot ulcers with wound areas measuring no larger than 16 $cm^{2,}$ 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.	Indicated to provide acoustic pressure shockwaves in the treatment of chronic, full-thickness diabetic foot ulcers with wound areas measuring no larger than 16 cm^2, 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.	**Same**
Product Class	II	II	**Same**
Classification Panel	General and Plastic Surgery Devices	General and Plastic Surgery Devices	**Same**
Product Code and Regulation	21 CFR 878.4685	21 CFR 878.4685	**Same**
Modes of Action	Focused Pressure Pulses	Focused Pressure Pulses	**Same**
Mechanism of Action	Extracorporeally induced pressure pulses	Extracorporeally induced pressure pulses	**Same**
Operating Mode	Continuous	Continuous	**Same**

Product Characteristic	**Subject Device CS-Pro MED**	**DuoLith SD1 with C-ACTOR**	**Comparison**
Focus Depth Range	0 - 30mm	0 - 30 mm	**Same**
Energy Flux Density (EFD) Setting Range	0.02 - 0.22mJ/mm^2	0.03 - 1.24mJ/mm^2	**Not Significantly Different**
Number and Size of Treatment Applicator Heads	5 standoffs 58 x 38mm	ø62 x 179 mm	**Not Significantly Different**
Device / Transducer Lifetime	5M shocks	5M shocks	**Same**
Pulse Repeat Rate	2 - 12 Hz	1 - 8 Hz	**Not Significantly Different**
Adustable Number of Pulses (min and max)	Variable, 100 - 5000	Variable, 100 - 3000	**Not Significantly Different**
Operating Temperature	5° – 37°C	10° – 30°C	**Not Significantly Different**
Weight and System Dimensions (WxHxD)	3.7 kg 203 x 76 x 44.5 mm	Unknown 454 x 187 x 460 mm	**Different** Subject Device is significantly smaller in size and lighter in weight.
Type of Acoustic Wave Generation	Piezoelectric, high voltage pulse applied to an array of transducers	Electromagnetic, pressure wave under water caused by discharge of high voltage condensers	**Not Significantly Different** Differences are caused by alternative technology used to generate acoustic shock waves.
User Interface	Touch Screen	Touch Screen	**Same**

Product Characteristic	Subject Device CS-Pro MED	DuoLith SD1 with C-ACTOR	Comparison
Power Supply	3.7 VDC, 2300 mAh, 8.5 Wh Lithium-ion battery	100 – 240 VAC (AC-mains)	**Different** Subject Device is battery powered whereas predicate is AC-mains powered.
Treatment Duration	5 - 10 min	10 - 20 min	**Not Significantly Different**

Energy Flux Density (EFD) Setting Range – The subject device uses alternative technology that is more suitable for a handheld, battery-operated device. The EFD range of the subject device is lower or within the setting range of the predicate device.

Number and Size of Treatment Standoff Heads – The number of standoff heads is different from the predicate device, but the area of the subject device standoff heads in contact with the patient is comparable and within the range of contact area of application pads / heads of the predicate device. All materials in contact with patient have been assessed for biocompatibility.

Pulse Repeat Rate – The subject device can be configured to administer 2 to 12 shock wave pulses per second (2 to 12 Hz), whereas the predicate can be configured to administer between 1 and 8 shock wave pulses per second. (1 to 8 Hz). Shock wave pulses from subject device are on the order of 2 microseconds in total duration. At the maximum pulse repeat rate setting for subject device (12 Hz), the device administers energy for only 24 microseconds per second, or put another way, the device is **not** administering energy 99.9976% of the time. There is no significant difference between 8 Hz and 12 Hz maximum pulse repeat rate.

Adjustable Number of Pulses – The subject device allows the clinician to set the number of pulses per treatment as needed between 100 and 5,000 pulses. This parameter is similar to that of the predicate device. This difference is not significant and does not raise new questions of safety or effectiveness.

Operating Temperature – The subject device has a slightly broader operating temperature range than the predicate.

Weight and System Dimensions – The subject device is smaller and lighter in weight than the predicate, making it far more convenient for handheld use.

Type of Acoustic Wave Generation – The subject device provides therapy by means of extracorporeally induced acoustic pressure waves that are generated by means of a focused array of piezoelectric elements. The acoustic pressure waves are coupled to the patient tissue by means of an elastomeric standoff with

specific acoustic properties. This technology creates the same type of acoustic pressure wave as the predicate device, with comparable acoustic parameters thereby achieving the same mechanism of action.

Power Supply – The power supply of the subject device differs from that of the predicate. The subject device is powered by a 3.8 V, 2300 mAh, 8.5 Wh rechargeable lithium-ion battery, whereas the predicate device is powered from AC-mains power.

Treatment Duration – The subject device is able to deliver shock wave pulses at a higher pulse repeat rate, providing for shorter treatment durations compared to the predicate device. This difference is not significant and does not raise new questions of safety or effectiveness.

Substantial Equivalence

The CS-Pro MED is substantially equivalent to the predicate device DuoLith SD1 with C-ACTOR (K202112). The subject device is safe and effective for its intended use.

Any differences between the predicate and CS-Pro MED have no significant influence on the safety or effectiveness of the subject device. Therefore, the CS-Pro MED is substantially equivalent to the predicate device.

Conclusion

Based upon the intended use and known technical information provided in this pre-market notification, the CS-Pro MED has been shown to be substantially equivalent to the currently marketed predicate device.