7/11/22

EMS Electro Medical Systems SA
℅ Sheila Hemeon-Heyer
President
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, Massachusetts 01002

Re: K220538
Trade/Device Name: DolorClast® Radial
Regulation Number: 21 CFR 890.5660
Regulation Name: Therapeutic massager
Regulatory Class: Class I
Product Code: ISA
Dated: February 25, 2022
Received: February 25, 2022

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/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 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 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,

for Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220538

Device Name

DolorClast® Radial

Indications for Use *(Describe)*

The DolorClast® Radial is indicated for:

- Relief of minor muscle aches and pains
- Temporary increase in local blood circulation
- Activation of connective tissue

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:

EMS Electro Medical SA
Ch. de la Vuarpillière 31
1260 Nyon, Switzerland
Contact: Vivian Yee
Phone: +44 7305 232869
Email: vyee@ems-ch.com

B. Date Prepared: July 7, 2022

D. Device Name and Classification Information:

Trade name:	DolorClast® Radial
Common/Usual Name:	Therapeutic Electric Massager
Classification name:	Therapeutic Massager
Review Panel	Physical Medicine
Classification regulation:	21 CFR 890.5660
Product code:	ISA
Class:	Class I

E. Predicate Device(s): K173692, D-Actor® 200 Vibration Massage System

F. Device Description:

The DolorClast® Radial is a portable radial pressure pulse device with an integrated air compressor. The DolorClast® Radial system is composed of the DolorClast® Radial console, handpiece, interchangeable applicator heads, and optional cart. Swiss DolorClast® Gel, previously approved under P050004, is also provided for coupling the treatment applicator to the patient's skin.

The DolorClast® Radial console generates and controls the pressure pulse frequency and intensity. Air pressure from the console drives a projectile within the handpiece against the applicator head to generate the pressure pulses at the set frequency and intensity. Device activation is done by the practitioner via a trigger button on the handpiece. The applicator at the distal end of the handpiece transmits the radial pressure pulses to the targeted tissues via the coupling gel applied to the treated skin.

G. Indications for Use Statement

The DolorClast® Radial is indicated for:

- Relief of minor muscle aches and pains
- Temporary increase in local blood circulation
- Activation of connective tissue

H. Comparison with Predicate Device

Parameter	Proposed Device (K220538)	Predicate Device (K173692)	Comparison
Device Trade Name	DolorClast® Radial	D-Actor® 200 Vibration Massage System	N/A
Device Manufacturer	EMS Electro Medical System SA	Storz Medical AG	N/A
Indications for Use Statement	The DolorClast® Radial is indicated for: • Relief of minor muscle aches and pains • Temporary increase in local blood circulation • Activation of connective tissue	The D-Actor® 200 Vibration Massage System is intended for: • Relief of minor muscle aches and pains • Temporary increase in local blood circulation • Activation of connective tissue	Same
Mode of Action	Radial pressure waves, or extracorporeal pulse activation respectively	Radial pressure waves, or extracorporeal pulse activation respectively	Same
Mechanism of action	Pneumatically generated vibrations	Pneumatically generated vibrations	Same
System components	Control console with integrated air compressors to control treatment parameters Mains cable Handpiece containing projectile within guiding tube Interchangeable applicators Coupling gel Cart (optional)	Control unit Mains cable Handpiece containing projectile within guiding tube Interchangeable applicators Coupling gel Footswitch (optional) Tablet PC (optional)	Same except for optional accessories
Method of triggering vibration pulses	Handpiece	Handpiece or optional footswitch	Same except for predicate optionally can be controlled using a footswitch
Type of acoustic wave generation	Pneumatic/ballistic	Pneumatic/ballistic	Same
Pressure setting range	1-4 bar	1-5 bar	Similar
Frequency setting range	1-25 Hz	1-21 Hz	Similar
Number of treatment applicators	7	4	Similar
Treatment applicator sizes	OD in mm: 5, 10, 15, 25, 40	OD in mm: 6, 15, 20, 35	Similar
Projectile mass (g)	3.2	3	Similar
Displacement of applicator heads	0.18 - 0.28 mm	0.6 – 2.0 mm	Similar
Operating mode	Continuous vibration at a fixed frequency	Continuous vibration at a fixed frequency	Same

Parameter	Proposed Device (K220538)	Predicate Device (K173692)	Comparison
Maximum penetration depth	40 mm	32.3 mm	Similar
Number of pulses per treatment	Variable as set by operator Max 5 000 pulses/treatment	Variable Max not publicly available	Similar
Maximum energy flow density	0.29 mJ/mm^2 at 4 bar 0.14 mJ/mm^2 at 2.4 bar	0.284 mJ/mm^2 at 5 bar 0.176 mJ/mm^2 at 3 bar	Similar
Maximum positive peak pressure amplitude	17 MPa at 4 bar 11.24 MPa at 2.4 bar	18.5 MPa at 5 bar 13.4 MPa at 3 bar	Similar
Maximum negative peak pressure amplitude	10 MPa at 4 bar 7.2 MPa at 2.4 bar	6.8 MPa at 5 bar 5.0 MPa at 3 bar	Similar
Derived focal acoustic pulse energy	5.9 mJ at 4 bar* 2.2 mJ at 2.4 bar*	6.5 mJ at 5 bar 2.4 mJ at 3 bar	Similar
Derived pulse-intensity integral (max), integrated over total temporal integration limits (mJ/mm^2)	0.29 mJ/mm^2 at 4 bar 0.14 mJ/mm^2 at 2.4 bar	0.284 mJ/mm^2 at 5 bar 0.176 mJ/mm^2 at 3 bar	Similar
Rise time	3.2 µs	2.5 µs	Similar
Compressional pulse duration	2.6 µs (1st peak) 62.7 µs (1st phase)	Ultrasonic pulse: 5.0 µs Sonic pulse: 50 µs – 5.0 ms	Similar
Power supply	Mains power	Mains power	Same
Operating temperature range	10˚C - 30˚C	10 ˚C - 40˚C	Similar
Control console dimensions	450 x 340 x 180 mm 17.7 x 13.4 x 7.1 inches	Not publicly available	-
Control console weight	14.5kg	Not publicly available	-

*Averaged across all applicator sizes.

I. Substantial Equivalence Discussion

The DolorClast® Radial has the same indications for use and mechanism of action as the predicate D- Actor® 200. Both use compressed air to drive a projectile against a stainless steel applicator in contact with the skin, transferring low-amplitude pressure pulses to the treatment target via standard coupling gel. Both devices are operated using a handpiece; however, the predicate device can also optionally be operated using a footswitch. There are minor differences in the technical characteristics of the pressure pulses. The maximum pulse pressure setting of the DolorClast® Radial is slightly lower than the D-Actor® 200 Vibration Massage System (4 bar vs 5 bar, respectively), while the maximum pulse frequency setting of the DolorClast® Radial is slightly higher than the D-Actor® 200 Vibration Massage System (25Hz vs 21Hz, respectively). The DolorClast® Radial has more options for applicators than the D-Actor® 200 Vibration Massage System (7 vs 4, respectively); however, the applicator size ranges for the two devices are very similar. The technical characteristics of the pressure pulses are very similar between the two devices. In particular, the maximum energy flux density is nearly identical at 0.29 mJ/mm^2 for the DolorClast® Radial and 0.28mJ/mm^2 for the D-Actor® 200 Vibration Massage System. The DolorClast® Radial applicator heads demonstrate less movement than the D-Actor® 200

Vibration Massage System, ranging from 0.18 to 0.28 mm depending on applicator size for the DolorClast® Radial versus 0.6 to 2.0 mm for the D-Actor® 200 Vibration Massage System. However, the role of the applicator is to transfer the pressure pulse energy from the handpiece piston to the treatment site, which is independent of applicator movement. The technical differences do not present any new risks or raise any new questions of safety or effectiveness.

J. Summary of Data Submitted to Support Substantial Equivalence

The following testing was included in this 510(k) to support substantial equivalence:

System functional performance testing

- The operation of the DolorClast® Radial air compressors was tested under an internal EMS protocol to confirm that the compressors were only activated when the handpiece trigger was pressed and to verify that the pressure output at each pressure setting met the pre - defined pressure setting tolerance. All tests were passed.
- The operation of the DolorClast® Radial console was tested under an internal EMS protocol to confirm correct operation of the console at all treatment settings, including for the Smart Protocols and Special Modes. Testing included error conditions to verify correct device response. All tests were passed.
- The operation of the DolorClast® Radial handpiece was tested under an internal EMS protocol to confirm correct operation of the handpiece including adjustment of the pressure, starting and stopping treatment, and recording piston use information. All tests were passed.
- Acoustic output testing was conducted to characterize the output pressure wave for each of the system applicators on the following parameters:
    - Displacement of applicator heads
    - Maximum penetration depth
    - Energy flow density
    - Positive and negative peak pressure amplitudes
    - Derived focal acoustic pulse energy
    - Derived pulse-intensity integral
    - Rise time
    - Compressional pulse duration

Lifetime Testing

Testing was conducted under internal EMS protocols to confirm that the DolorClast® Radial console, handpiece, and applicators continued to function and meet their performance specifications for the claimed useful lifetimes of:

- Console: 7 years or 50,000,000 pulses
- Handpiece: 2 years or 5,000,000 pulses
- Applicators: 2 years or 5,000,000 pulses

Biocompatibility

The only components of the DolorClast® Radial system that come into contact with the patient are the applicator tips and the Swiss DolorClast® gel, both of which are in contact with intact skin for less than 24 hours. Cumulative use may exceed 24 hours for heavy users. The Swiss DolorClast® gel was previously approved under P050004 and has not changed since that time. The applicators are made of the same stainless-steel material as the applicators for the Swiss DolorClast® applicators, previously approved under P050004, and there have been no changes to the applicator material, manufacturing processes, or patient contact category since that time. Therefore, the prior biocompatibility testing conducted to support P050004 remains applicable for both the applicators and the gel, and no further biocompatibility testing was required to support the DolorClast® Radial 510(k) application.

Transportation Testing

Transportation testing was conducted for the DolorClast® Radial system in accordance with the International Safe Transit Authority standards ISTA 2A and ISTA 3A. Packages were visually inspected after being subjected to environmental and mechanical conditioning. The device and device accessories were tested for functionality following the package conditioning. All tests were passed.

Software Validation

The DolorClast® Radial software was evaluated as having a moderate level of concern. The 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 both software testing and system level testing with the software integrated into the final device.

Electrical Safety and EMC

The DolorClast 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

K. Conclusion

The information presented in this 510(k) demonstrates that the DolorClast® Radial is substantially equivalent to the predicate device as a Class I therapeutic massager under 21 CFR 890.5660, Product Code ISA.