April 13, 2018

Storz Medical AG
% Michael Dayton
President
Biomed Research, Inc.
3959 Van Dyke Road
Suite 245
Lutz, Florida 33558

Re: K173692
Trade/Device Name: D-Actor 200 Vibration Massage System
Regulation Number: 21 CFR 890.5660
Regulation Name: Therapeutic Massager
Regulatory Class: Class I
Product Code: ISA
Dated: April 5, 2018
Received: April 9, 2018

Dear Mr. Dayton:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173692

Device Name
D-ACTOR® 200 Vibration Massage System

Indications for Use *(Describe)*
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

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

Storz Medical AG

D-ACTOR® 200 Vibration Massage System

1. SPONSOR

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Switzerland

Contact Person: Pavel Novak, Ph.D.
Telephone: 41 (0) 71 677 45 13
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Date Prepared: April 5, 2018

2. DEVICE NAME

Proprietary Name:	D-ACTOR® 200 Vibration Massage System
Common/Usual Name:	Therapeutic Electric Massager/Vibrator
Classification Name:	Massager, Therapeutic, Electric
Review Panel:	Physical Medicine
Regulations Number:	890.5660
Product Code:	ISA
Device Class:	1

3. PREDICATE DEVICES

Equivalence claimed to the Acoustic Wave (AW) module component (i.e., D-Actor Vibration Massage System provided OEM) of the Dermablate Effect, submission number K081541 and the TattooStar Effect Y, submission number K112669.

AW Module (D-Actor provided OEM):

Classification Name:	Massager, Therapeutic, Electric
Product Code:	ISA
Device Class:	1

4. DEVICE DESCRIPTION

The D-ACTOR® handpiece uses pressurized air pulses to accelerate a projectile within a guiding tube. The accelerated projectile hits a skin-contacting steel activator which is dampened by elastic O-rings that affix it to the distal end of the handpiece and a vibration absorber at proximal end of the handpiece. When the projectile impacts the activator, slow-rising, low-amplitude pressure pulses are generated. Standard coupling gel is typically used to reduce the loss of pulse amplitude to surrounding air. The D-ACTOR 200 System consists of a Control Unit, Handpiece, Mains Cable, Commercially available coupling gel, Foot switch (optional), and Tablet PC (optional). The password protected GUI interface software allows the operator to create, save and edit treatment programs for application to various muscle groups, and permits the operator to create, edit and save individual patient treatment program routines and progress notes. Various software features permit the operator to: (1) adjust energy level, number of pulses, frequency and total pulses delivered, (2) display and adjust skin contact intensity of the applicator, (3) save treatment images/videos to track progress, and (4) utilize Visible Body® interactive 3D musculature to allow the operator to "mark" and save treatment regions to patient records.

5. INTENDED USE

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

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The technological characteristics of the D-ACTOR® 200 device and the predicate devices are substantially equivalent in that each device is designed to use pressurized air pulses to accelerate a projectile within a guiding tube that hits a skin-contacting steel activator. When the projectile impacts the activator, slow-rising, low-amplitude pressure pulses are generated. Standard coupling gel is used to reduce the loss of pulse amplitude to surrounding air. The D-ACTOR® 200 and the predicate devices employ the same principles of operation. The D-ACTOR® 200 is substantially equivalent in function, purpose and design to the predicate devices and other legally marketed therapeutic massagers and vibrators.

7. PERFORMANCE TESTING

Verification and validation testing was performed and demonstrated that the D-ACTOR® 200 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 D-ACTOR® 200 software was validated and demonstrated to be of a Moderate level of concern; while hazard analysis / risk management was performed and demonstrated that all risks are mitigated to an acceptable level. The skin contacting component was tested for biocompatibility and found to conform to elements of ISO 10993-1:2003. The D-ACTOR® 200 was tested and demonstrated to conform to the general safety requirements of IEC 60601-1:2012 (Ed. 3.1); as well as the electromagnetic compatibility requirements of IEC 60601-1-2:2007 (3rd Ed.).

In-vitro testing was performed to determine applicator displacement, force and penetration depth and was demonstrated to be equivalent to the AW module (i.e., D-ACTOR provided as OEM) of the predicate devices. Ultrasonic energy comprises approximately 5% of D-ACTOR® 200 total output and this parameter was evaluated by employing modified protocols from IEC 61846. Those tests demonstrated energy flow densities (ED) of 0.176mJ/mm2 at 3 bar pressure (same ED as the predicates) and 0.284mJ/mm2 at 5 bar pressure.

There are no performance standards applicable to the D-ACTOR device adopted under Section 514 of the Act. However, in addition to the international consensus standards cited above, the D-ACTOR® 200 also complies with the applicable requirements of the following international standards:

- ISO 14971:2000/A1:2003: Medical devices: Application of risk management to medical devices.
- IEC 62304:2006: Medical Device Software – Software Life Cycle Process.
- IEC 61000-3-2:2000: Electromagnetic compatibility (EMC): Limits – Limits for harmonic current emission.
- IEC 61000-3-3:2000: Electromagnetic compatibility (EMC): Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems.

The performance testing demonstrated that the D-ACTOR® 200 is substantially equivalent to the predicate devices and that it is safe and effective for its intended use. The table below compares D-Actor® 200 characteristics to the predicate devices.

Substantial Equivalence Comparison

Product Characteristic	**D-Actor® 200**	**AW Module of Predicates Dermablate & TattooStar**
Indications for Use	*Relief of minor muscle aches and pains *Temporary increase in local blood circulation *Activation of connective tissue	Same
Modes of Action	Radial pressure waves, or extracorporeal pulse activation respectively	Same
Mechanisms of Action	Pneumatically generated vibrations	Same
Maximum and Minimum intensity settings	1-5bar	1-5bar and 1-3bar
Number and size of treatment applicator heads	4: 6mmOD, 15mmOD, 20mmOD, 35mmOD	3: 6mmOD, 15mmOD, 20mmOD and 2: 20mmOD, 35mmOD
Maximum and minimum displacements of applicator heads	0.6 – 2.0mm	0.6 – 2.0mm and 2.0mm
Type of application (e.g., continuous vibration at a fixed frequency);	Continuous vibration at a fixed frequency	Same
Maximum and minimum vibration frequency	1-21Hz	0.5-21Hz and 0.5-3Hz
Driving Power	1-5bar	1-5bar and 1-3bar
Power Supply	500VA	Same
Maximum penetration depth	32.3mm	17mm and 32.3mm
Energy flow density	Values of ultrasonic pulse: 5bar/0.284mJ/mm^2 3bar/0.176mJ/mm^2	Value of ultrasonic pulse: 3bar/0.176mJ/mm^2
Operating mode	Continuous	Same
Projectile mass (g)	3	Same
Pulse repeat rate (1/s)	1-21Hz	0.5-21Hz and 0.5-3Hz
Number of pulses (min and max)	Variable	Same
Maximum operating temperature	10-40°C	Same
Type of acoustic wave generation	Pneumatic/ballistic	Same
Positive peak pressure amplitude (MPa)	Values of ultrasonic pulse: 5bar/18.5MPa 3bar/13.4MPa	Value of ultrasonic pulse: 3bar/13.4MPa
Negative peak pressure amplitude (MPa)	Values of ultrasonic pulse: 5bar/6.8MPa 3bar/5.0MPa	Value of ultrasonic pulse: 3bar/5.0MPa
Derived focal acoustic pulse energy (mJ)	Values of ultrasonic pulse: 5bar/6.5mJ 3bar/2.4mJ	Value of ultrasonic pulse: 3bar/2.4mJ
Derived pulse-intensity integral, integrated over total temporal integration limits (mJ/mm2)	Values of ultrasonic pulse: 5bar/0.284mJ/mm^2 3bar/0.176mJ/mm^2	Value of ultrasonic pulse: 3bar/0.176mJ/mm^2
Rise time (ns)	Ultrasonic pulse: 2.5µs Sonic pulse: 25µs – 2.5ms	Same
Compressional pulse duration (µs)	Ultrasonic pulse: 5.0µs Sonic pulse: 50µs – 5.0ms	Same