February 21, 2021

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

Re: K202112
Trade/Device Name: Storz Medical DUOLITH SD1 T-Top & Tower System with C-ACTOR Sepia Handpiece
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: January 20, 2021
Received: January 22, 2021

Dear Michael 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. 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,

Long Chen, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202112

Device Name
DUOLITH SD1 T-Top & Tower System with C-ACTOR Sepia Handpiece

Indications for Use *(Describe)*
The DUOLITH SD1 T-Top & Tower System with C-ACTOR Sepia Handpiece is indicated 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 DUOLITH SD1 with C-ACTOR 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.

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510(k) Summary

1. SPONSOR

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Date Prepared: February 19, 2021

2. DEVICE NAME

Proprietary Name:	DUOLITH SD1 T-Top & Tower System with C-ACTOR Sepia Handpiece
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
Device Class:	II

3. PREDICATE DEVICES

Equivalence is claimed to the predicate devices: DERMAPACE device (DEN160037; primary) and the ORTHOGOLD device (K191961).

4. DEVICE DESCRIPTION

The DUOLITH SD1 with the C-ACTOR Sepia Handpiece uses an electromagnetically generated shock wave produced within the hand-held applicator. The shock wave is generated by discharging a high voltage capacitor located in the Control Unit into a cylindrically shaped coil system in the C-ACTOR Handpiece which is surrounded by a cylindrical metallic membrane. The transient magnetic field produced by the coil induces eddy currents in the metal membrane, causing it to repel from the coil, producing a pressure wave. The membrane is immersed in water and the pressure wave produced by the membrane propagates through the water to a concentric parabolic reflector, where it is reflected to a focal point outside of the Handpiece in front of the reflector. The DUOLITH SD1 with C-ACTOR incorporates micro-processor control of the operating parameters.

5. INTENDED USE

The DUOLITH SD1 C-ACTOR Handpiece is 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. The DUOLITH SD1 with C-ACTOR 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.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The technological characteristics of the DUOLITH SD1 and the predicate devices are the same with the exception of acoustic wave generation. The predicate devices utilize a high voltage spark plug to initiate a shock wave, while the Duolith utilizes a high voltage electrical coil. Both methods generate a short, high amplitude pulse (shock wave) of about 5 micro-seconds duration and results in similar waveforms and output energies.

7. PERFORMANCE TESTING

Nonclinical Performance

Nonclinical verification and validation testing was performed and demonstrated that the DUOLITH SD1 with C-ACTOR 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 DUOLITH SD1 with C-ACTOR is substantially equivalent to the predicate devices.

The DUOLITH SD1 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. There are no direct body contacting components since the treatment handpiece is separated from direct patient contact by a sterile barrier during treatment. However the treatment head component was nevertheless tested for biocompatibility (contact duration <24 hours) and found to conform to elements of ISO 10993-1:2009. The DUOLITH SD1 was tested and demonstrated to conform to the general safety requirements of IEC 60601-1:2012; IEC 60601-6:2013; and electromagnetic compatibility requirements of IEC 60601-1-2:2014; and the RFID electromagnetic immunity requirements of AMI 7351731.

No performance standards applicable to this device have been adopted under Section 514 of the Act. The DUOLITH SD1 System with C-ACTOR complies with the applicable requirements of the following international consensus standards:

- ISO 14971: 2007: Medical devices: Application of risk management to medical devices.

- ISO 10993-1:2009 (4th Ed.): Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process.
- ISO 61846:1998 Ultrasonics - Pressure pulse lithotripters - Characteristics of fields.
- IEC 60601-1:2012, (3rd Ed.): Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- IEC 60601-2-36: 2014 (2nd Ed.): Medical electrical equipment – Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy.
- IEC 60601-1-2: 2014 (4th Ed.): Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.
- IEC 60601-1-6: 2013 (3.1 Ed.): Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
- AIM 7351731:2017 (Rev. 2.0): Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers.
- IEC 62304:2015 (1.1 Ed.) Medical Device Software – Software Life Cycle Process.
- ISO 13485:2016: Medical devices – Quality management systems – Requirements for regulatory purposes.

Clinical Performance

A review of published literature with the subject device demonstrated successful clinical use with the Duolith SD1 technology in both men and women with 89 chronic soft tissue wounds having a range of etiologies including diabetes mellitus. The reports from five independent studies show significant results in complete wound healing (54-70% at 13-20 weeks) and reduction of wound area (35-80% at 7-20 weeks). The data from these studies establish the effectiveness of the Duolith SD1 to treat 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.

The conclusions drawn from the nonclinical and clinical tests demonstrate that the Duolith SD1 is as safe, as effective, and performs as well as the legally marketed predicate devices.

8. SUBSTANTIAL EQUIVALENCE COMPARISON

Product Comparison	Predicate Device dermaPACE	Predicate Device OrthoGold 100	Subject Device DUOLITH SD1 w/ C-ACTOR
510(k) Number	DEN160037	K191961	K202112
Product Class	II	- Same -	- Same -
Classification Panel	General and Plastic Surgery Devices	- Same -	- Same -

Product Code and Regulation	21 CFR 878.4685 PZL – Extracorporeal Shock Wave Device for Treatment of Chronic Wounds	Same	- Same -
Indications for Use	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 -	- Same -
Modes of action	Focused pressure pulses	Unfocused pressure pulses	Focused pressure pulses
Mechanism of action	Extracorporeally induced pressure pulses	- Same -	- Same -
Operating mode	Continuous	- Same -	- Same -
Electrical Protection	Class I, B	- Same -	- Same -
User Interface	LCD with function keys	Touch Screen	Touch Screen
Firmware Controlled	Yes	Yes	Yes
Type of Energy	Pressure pulses	- Same -	- Same -
Energy Source	100 – 240 V AC, 50–60 Hz	- Same -	- Same -
Type of Acoustic Wave Generation	Electrohydraulic, pressure wave under water caused by discharge of high voltage condensers	Electrohydraulic, pressure wave under water caused by discharge of high voltage condensers	Electromagnetic, pressure wave under water caused by discharge of high voltage condensers
Selection of parameters (Intensity, Frequency, Number of Pulses)	Yes	Yes	Yes
Size of treatment applicator heads	ø70 x 160 mm	ø70 x 230 mm	ø62 x 179 mm
Intensity Settings Range (Min-max: Energy Flux Density)	1 to 6 (0.23 - 0.33mJ/mm^2)	1 to 16 (0.01 - 0.19mJ/mm^2)	0.03 - 1.24mJ/mm^2
Focus depth	1.5 - 10.5mm	0 - 38mm "unfocused"	0 - 30mm
Pulse repeat rate (l/s)	1 - 4 Hz	1 - 8 Hz	1 - 8 Hz
Number of pulses (min and max)	31.25 - 500	100 - 1000	100 - 500
System Dimensions (W x H x D)	473 x 219 x 427 mm	400 x 218 x 459 mm	454 x 187 x 460 mm
Operating Temperature	N / A	10° – 30°C	10° – 30°C
Operating Relative Humidity	N / A	3 - 85%	5 - 55%
Treatment Duration (Typical)	5 – 10 min	10 – 20 min	10 – 20 min