May 3, 2021

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

Re: K203710
Trade/Device Name: Storz Medical MAGNETOLITH Muscle Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, NGX
Dated: February 1, 2021
Received: February 3, 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,

Patrick Antkowiak -S

Patrick Antkowiak, PhD
Assistant Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203710

Device Name

MAGNETOLITH Muscle Stimulator

Indications for Use *(Describe)*

The MAGNETOLITH Muscle Stimulator is indicated for:

-Relaxation of muscle spasms,
-Prevention or retardation of disuse atrophy,
-Increase local blood circulation,
-Muscle re-education,
-Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis,
-Maintaining or increasing range of motion.

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

Storz Medical AG

MAGNETOLITH Muscle Stimulator

1. SPONSOR

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Switzerland

Contact Person: Pavel Novak, Ph.D.
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Date Prepared: May 3, 2021

2. DEVICE NAME

Proprietary Name: MAGNETOLITH
Regulation Name: Powered Muscle Stimulator

Regulation Number: 21 CFR 890.5850
Product Code: IPF, NGX
Regulatory Class: II

3. PREDICATE DEVICES

Equivalence is claimed to the following predicate devices: HPM-6000 (K160992, primary), and Bemer Classic & Pro (K151834, secondary).

4. DEVICE DESCRIPTION

The MAGNETOLITH delivers electromagnetic pulses to stimulate muscle tissues by applying the Magnetic Induction Field Principle (high-energy magnetic pulses) directly over (but not in direct contact with) the patient in order to achieve the same powered muscle stimulation without having to place adhesive electrode pads directly onto the patient's body. Key components of the device are the Control Unit, Handpiece Applicator, Applicator holder, a Mains cable, and a Trolley. These device components are provided non-sterile and are intended to be reusable.

The principle of operation of the MAGNETOLITH is by the application of a treatment coil to generate electromagnetic induction, i.e., the production of voltage across an

electrical conductor in a changing magnetic field. The duration of the individual pulses is short and therefore the system does not increase temperature within the tissues. In addition, the MAGNETOLITH Applicator is cooled by circulating water.

5. INTENDED USE

The MAGNETOLITH is indicated for

- Relaxation of muscle spasms,
- Prevention or retardation of disuse atrophy,
- Increasing local blood circulation,
- Muscle re-education,
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis,
- Maintaining or increasing range of motion.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The technological characteristics of the MAGNETOLITH device and the predicate device is substantially equivalent in that each device is designed to non-invasively use electromagnetic induction to initiate action potential of nerves resulting in muscle contraction.

7. PERFORMANCE TESTING

Verification and validation testing was performed and demonstrated that the MAGNETOLITH 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 MAGNETOLITH 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. While the MAGNETOLITH has cleaning and sanitation requirements, there are no body contacting components and therefore biocompatibility testing was not performed. The MAGNETOLITH 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.

No performance standards applicable to this device have been adopted under Section 514 of the Act. The MAGNETOLITH complies with the applicable requirements of the following international consensus standards:

- ISO 14971:2000/A1:2007: Medical devices: Application of risk management to medical devices.

- IEC 60601-1:2012, (Ed. 3.1): Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- 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: 2012 (3.1 Ed.): Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
- IEC 62304:2015: Medical Device Software – Software Life Cycle Process.
- ISO 13485:2016: Medical devices – Quality management systems – Requirements for regulatory purposes.

The performance testing demonstrated that the MAGNETOLITH Muscle Stimulator is substantially equivalent to the predicate devices and that it is as safe, as effective, and performs as well as or better than the predicate devices. The table below compares the characteristics of the MAGNETOLITH to the predicate devices.

8. SUBSTANTIAL EQUIVALENCE COMPARISON

510(k) number **Device name** **Company name**	**K160992** HPM-6000 BTL Industries, Inc.	**K151834** Bemer Classic & Pro Bemer Int'l AG	**K203710** MAGNETOLITH Storz Medical AG	**Comparison**
Product Code and Regulation	Physical Medicine 21 CFR 890.5850 IPF - Stimulator, Muscle, Powered	Physical Medicine 21 CFR 890.5850 NGX - Stimulator, Muscle, Powered	Physical Medicine 21 CFR 890.5850 IPF - Stimulator, Muscle, Powered NGX - Stimulator, Muscle, Powered	**Same**
Intended Use / Indications for Use	The HPM-6000 device is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. The HPM-6000 device is indicated for use in stimulating neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes. Indications for Use for Muscle Stimulators: -Relaxation of muscle spasms -Prevention or retardation of disuse atrophy -Increasing local blood circulation -Muscle re-education -Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis -Maintaining or increasing range of motion	Indications for Use: -To temporarily increase local blood circulation in healthy leg muscles -To stimulate healthy muscles in order to improve and facilitate muscle performance	Indications for Use: -Relaxation of muscle spasms -Prevention or retardation of disuse atrophy -Increasing local blood circulation -Muscle re-education -Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis -Maintaining or increasing range of motion -To stimulate healthy muscles in order to improve and facilitate muscle performance	**Similar**

Principle of Action	Non- invasive tissue stimulation via magnetic field induction	Non- invasive tissue stimulation via magnetic field induction	Non- invasive tissue stimulation via magnetic field induction	**Same**
Clinical Use	Prescription use	Over the counter use	Prescription use	**Same**
Electrical Protection	Class II, BF	unknown	Class I, B	**Similar**[1]
User Interface	Touch screen	Touch screen	Touch Screen	**Same**
Firmware Controlled	Yes	Yes	Yes	**Same**
Type of Energy	Magnetic field	Magnetic field	Magnetic field	**Same**
Number of outputs	1	2	1	**Same**
Number of Magnetic Coils in the Applicator	1	unknown	1	**Same**
Magnetic Field Intensity	BTL 299-1 applicator: 0.5 - 1.8 T BTL 299-2 applicator: 0.7 - 2.5 T	35-100 µT	0.4T ±20% at surface 0.08T ±20% at center of coil	**Similar**
Pulse Repetition Rate	1 – 150 Hz	10-30 Hz	1-10Hz	**Similar**
Pulse Duration	BTL 299-1 applicator: 280µs ± 20% BTL 299-2 applicator: 280µs ± 20%	10-33µs	125µs ± 20%	**Similar**
Therapy Time	Up to 60 min	20 minutes	10-20 minutes	**Similar**
Energy Source	100 – 240 VAC, 50–60 Hz	100 – 240 VAC, 50/60 Hz	100 – 240 VAC, 50/60 Hz	**Same**
System Dimensions (W×H×D)	500×970×580 mm (20×38×23 in)	320 x 320 x 70 mm	454 x 187 x 460 mm	**Similar**
Ambient Temperature	10° - 30°C	10° – 30°C	10° – 30°C	**Same**
Relative Humidity	30 - 75%	unknown	5-55%	**Similar**
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only	**Same**

[1]**Electrical Protection:** The electrical security measures in devices are slightly different, but both comply with the IEC60601-1 standard for basic safety and essential performance.