February 25, 2025

CPMT LASER (Canadian Pioneer Medical Technology Corporation)
Dr. Rashid Reza Mir Sayah
Managing Director
460 Garyray Drive, North York
Toronto, ON M9L1P8
Canada

Re: K241601
Trade/Device Name: EMS (FlexPulse, MagnaCore, Magnetika)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: June 4, 2024
Received: June 4, 2024

Dear Dr. Sayah:

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,

Tushar Bansal -S

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241601

Device Name

Electromagnetic Stimulator Device (FlexPulse, MagnaCore, MagnetiKa)

Indications for Use *(Describe)*

The device is indicated to be used for:
• Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen.
• Strengthening, Toning and Firming of buttocks and thigh

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

Submitter:
CPMT Laser (Canadian Pioneer Medical Technology Corporation)
460 Garyray Drive #1, North York, Toronto, ON, M9L 1P8, Canada
Contact Person:
Dr. Rashid Reza Mir Sayah
Phone: (437) 772-7788
Email: canadianpioneer@yahoo.com
Date Prepared: February 10, 2025

Subject Device:
Trade/Device Name: Electromagnetic Stimulator Device
Models: FlexPulse, MagnaCore, MagnetiKa
Regulation Number: 21CFR 890.5850
Regulation Name: Stimulator, Muscle, Powered, For Muscle Conditioning
Regulatory Class: II
Product code: NGX
510(k) number: K241601
Manufacturer: CPMT Laser (Canadian Pioneer Medical Technology Corporation)

Predicate Device:
Trade/Device Name: BTL 799-2
Regulation Number: 21CFR 890.5850
Regulation Name: Stimulator, Muscle, Powered, For Muscle Conditioning
Regulatory Class: II
Product code: NGX
510(k) number: K180813
Manufacturer: BTL Industries, Inc.

Device Description:
The Electromagnetic Stimulator Device, with models FlexPulse, MagnaCore, and MagnetiKa, consists of a main unit, handpiece tools, and a power cable. The main unit has a power supply unit, a control unit, and a cooling unit. The control unit has a control element and a liquid crystal display. The handpiece tools have electromagnetic induction coils and cooling fans, it is a non-invasive device.

The device generates an electromagnetic field that interacts with human body tissues, aiding in muscle stimulation to strengthen and tone the abdomen, buttocks, and thighs. With two outputs, it allows simultaneous treatment using two applicators.

Indications for Use:

The device is indicated to be used for:

• Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen.

• Strengthening, Toning and Firming of buttocks and thighs.

Comparison of Technological Characteristics with the Predicate Device:

Substantial equivalence discussion

The comparison and discussion between the subject device and the predicate device is listed in the table below:

Table: Substantial equivalence comparison

	Subject Device	Predicate Device	Reference Device	Comparison
510(K)	K241601	K180813	K190456	-
Manufacturer	CPMT Laser	BTL Industries, Inc.	BTL Industries, Inc.	-
Trade Name	EMS	BTL 799-2	BTL 799-2L	-
Regulation number	21 CFR 890.5850	21 CFR 890.5850	21 CFR 890.5850	Identical (the same)
Regulation Name	Powered muscle stimulator	Powered muscle stimulator	Powered muscle stimulator	Identical (the same)
Product code	NGX	NGX	NGX	Identical (the same)
Class	II	II	II	

Indications for use/Intended use	The device is indicated to be used for: • Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen. • Strengthening, Toning and Firming of buttocks and thighs.	The device is indicated to be used for: • Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen. • Strengthening, Toning and Firming of buttocks and thighs.	The device is indicated to be used for: • Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen. • Strengthening, Toning and Firming of buttocks and thighs.	Identical

Primary Function	Muscle stimulation	Muscle stimulation	Muscle stimulation	Identical
Principal of Action	Initiating action potential of nerves results in muscle contraction	Initiating action potential of nerves results in muscle contraction	Initiating action potential of nerves results in muscle contraction	Identical
User Interface	Touch screen	Touch screen	Touch screen	Identical
Touch Screen size	15.6 inches	15.6 inches	15.6 inches	
Firmware Controlled	Yes	Yes	Yes	Identical
Type of Energy	Magnetic field	Magnetic field	Magnetic field	Identical
Magnetic Field Intensity (on the coil surface)	0.5-1.8T,±20%	299-6 applicator: 0.5–1.8 T	BTL 299-6 applicator: 0.5 - 1.8 T ,±20% BTL 299-7 applicator: 0.7 - 2.0 T ,±20%	Identical
Number of Outputs	2	2	2	Identical

Maximum Magnetic Field Intensity at Applicator Center Surface	1.0T±20%	BTL 299-6 applicator: 1.154 T±20%;	BTL 299-6 applicator: 1.154 T±20%; BTL 299-7 applicator: 1.173 T±20%.	The maximum field intensity at the center surface of the applicator is 1.0T, in comparison to 1.154T for the predicate device. Nonetheless, the magnetic field intensity falls within the acceptable range of the predicate device.
Number of Magnetic Coils in the Applicator	1	1	1	Identical
Type of Operation	Continuous	Continuous	Continuous	Identical
Pulse Repletion Rate	1 – 150 Hz	1 – 150 Hz	1 – 150 Hz	Identical

Pulse Duration	270 ±20% µs	280 ± 20% µs	BTL 299-6 applicator: 280 ± 20% µs BTL 299-7 applicator: 190 ± 20% µs	The subject device has a slightly shorter pulse width compared to the predicate device but falls within the range between the predicate and reference devices.
Pulse Amplitude	0 – 100%, step 1%	0 – 100%	Not publicly available	Identical
Selection of parameters (Intensity, Time)	Yes	Yes	Yes	Identical
Shape of Stimulation Pulse	Symmetrical Biphasic Sine Wave	Symmetrical Biphasic Sine Wave	Symmetrical Biphasic Sine Wave	Identical
Induced Current in the Tissues	20.6mA	28-30mA	Not Publicly Available	The current induced in the tissue by the subject device is lower than that of the predicate device, making it safer while achieving the same effect.
Therapy Time	Up to 60 min	Up to 60 min	Up to 60 min	Identical
Application	Hands-free, applicator fixed by fixation belt	Hands-free, applicator fixed by fixation belt	Hands-free, applicator fixed by fixation belt	Identical
Energy Source	100–240 VAC, 50–60 Hz	100–240 VAC, 50–60 Hz	100–240 VAC, 50–60 Hz	Identical

System Dimensions (WxHxD)	525x433x1279mm/ 640×560×1390mm	500×1380×580 mm (20x55x23 in)	500×1380×580 mm (20x55x23 in)	The varying dimensions do not impact the safety or effectiveness of the device.
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only	Identical
Ambient Temperature	-20°C ~ +55°C	-10°C to +55°C	-10°C to +55°C	This variation does not affect the safety or effectiveness of the device.
Conformance Standard	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-6; IEC 60601-2-10	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-6; IEC 60601-2-10	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-6; IEC 60601-2-10	Identical
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Identical

Summary of Non-Clinical Tests:

Non clinical tests were conducted to verify that the subject devices met all design specifications and was substantially equivalent (SE) to the predicate device. The test

results demonstrated that the proposed device complies with the following:

- ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) 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 compatibility - Requirements and tests
- IEC60601-2-10:2016, Medical electrical equipment -- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 60601-1-6: 2013, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

Software Verification and Validation Testing:

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software was considered as a "moderate" level of concern.

Conclusion

The EMS device is considered to have substantial equivalence to its predicate device. The intended uses of the proposed device are included within the scope of the predicate device. All three models fall under the umbrella of the predicate device.

Non-clinical testing has shown that the device is equally safe, effective, and is substantially equivalent to the legally marketed device.