June 10, 2022

Pain Management Technologies, Inc.
Joshua Lefkovitz
President
1760 Wadsworth Rd.
Akron, Ohio 44320

Re: K213097
Trade/Device Name: Armory Motion
Regulation Number: 21 CFR 890.5720; 21 CFR 890.5650
Regulation Name: Water Circulating Hot Or Cold Pack; Powered inflatable tube massager
Regulatory Class: Class II
Product Code: ILO, IRP
Dated: May 10, 2022
Received: May 18, 2022

Dear Joshua Lefkovitz:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213097

Device Name
Armory Motion

Indications for Use *(Describe)*
The Armory Motion is a prescription device that combines cold and compression therapy and is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain for which cold and compression are indicated.

Armory Motion is intended to be used by a licensed health care professional in rehabilitation facilities, outpatient clinics, athletic training settings, and home settings.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K213097

Date of Submission prepared: 16 August 2021

I Submitter : Pain Management Technologies, Inc.

Address: 1760 Wadsworth Rd. Akron, OH 44320, USA
Tel : 614-937-8236
Fax : 888-304-5454
E-Mail : josh@paintechnology.com
FDA Establishment
Registration No: 1528161
Contact person: Joshua A. Lefkovitz / President

Address of the manufacturing facility:

Manufacturer: EasyMed Instruments Co Ltd
Address: 3/F, 5F-6F, Block A, GupoGongmao Building, Fengxin Road, Fengxiang Industrial District, Daliang, 528300 Shunde, Foshan, Guangdong, China,
FDA Establishment
Registration No: 3004049909

II Submitted Device:

Trade name: Armory Motion
Common name: Cold and Compression Therapy
Classification Name: Powered Inflatable Tube Massager; Water circulating hot or cold pack
Classification Number: Title 21 CFR 890.5650; Title 21, CFR 890.5720
Product Code: IRP, ILO
Classification Panel: Neurological and Physical Medicine;
Regulatory Class: Class II

III Predicate Device:

Trade/Device Name: Cold and Compression Therapy
Model Number: Polar Care Wave™
Submitter: Breg, Inc.
510(k) Number: K183702
Product Code: IRP, ILO
Type of Use: Prescription

Classification: Class II

IV DEVICE DESCRIPTION

Armory Motion is a multimodality software-controlled device designed to provide both a muscle massage and a circulatory thermal therapy.

The Armory Motion is an AC Rechargeable Battery powered device designed to provide cold and intermittent Pneumatic Compression to a treatment site on the user. The device includes a lid with LCD panel, pump and electronics, a reservoir, tubing and a single-patient use, non-sterile, pneumatic air compression joint wrap that can also circulate water (dual bladder), to provide cold thermal therapy in addition to the compression. The Joint wrap can be used to treat the back, elbow, shoulder, foot, ankle, and knee.

The Armory Motion device contains several key parts: A cold-compression pad with a connector hose, an insulated container to hold ice and water, and a lid that contains a water pump and air pump, electronics to control the pumps, tubing, and an intuitive keypad to operate the device.

The cold-compression pads are connected to the lid tubing and are applied to the body to deliver cold and intermittent compression therapy. The cold compression pads are made of flexible materials that form two bladders. The dual bladder design allows cold water to continuously flow through one of the bladders to provide cold therapy, and air to be cyclically pumped into and released from a second bladder to provide intermittent pneumatic compression therapy.

The insulated container is filled with ice and water by the user. The water circulates through the cold compression pad to deliver cold therapy to the application site.

The lid which houses the electronics, water pump, and air pump, is sealed and not accessible by the user. The lid also houses the keypad, which controls the device and allows the user to select the therapies as directed by a healthcare professional.

V Indications for Use of the device

The Armory Motion is a prescription device that combines cold and compression therapy and is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain for which cold and compression are indicated.

Armory Motion is intended to be used by a licensed health care professional in rehabilitation facilities, outpatient clinics, athletic training settings, and home settings.

VI Equivalence Comparison to the Predicate Devices:

The technical characteristics of the applicant device (Model: Armory Motion) are similar to those of the predicate device in design, intended use and function. The predicate device Breg Polar Care Wave (K183702)., and the new device Armory Motion is a device that

utilize a pneumatically controlled compression wrap providing intermittent pressure to joints and the lower extremities of a patient.

The Breg Polar Care Wave (K183702) provides both intermittent pneumatically controlled compression and cold thermal therapy.

The table below summarizes the shared and unique technological elements between the Armory Motion and the predicate device. The technology, engineering, and performance for Armory Motion are substantially equivalent to the predicate device.

From the view of safety and effectiveness, the new device Armory Motion uses preset programs that are substantially equivalently to the predicated device. The output characteristics of Armory Motion are similar to those of predicated device, see Table below.

The new device Armory Motion is designed to comply with relevant safety applicable recognized consensus standards; the output pressure is controlled well within the safety and effectiveness ranges specified by relevant FDA guidance. Detailed and strictly controlled testing has been carried out.

Furthermore, Test results, Risk Analysis, and FMEA analysis show that the new device Armory Motion is safe with no hazard.

As such:
1. the new device (Model: Armory Motion) has the same technological characteristics and intended uses as the predicate devices, and
2. the information submitted to the FDA for the new device (Model: Armory Motion) does not raise new questions about safety or effectiveness and demonstrates with reasonable assurance based on established controls that the device is at least as safe and effective as a legally marketed device.

Table 1 Substantial Equivalence Comparison Table

510(K)No.:	**(to be assigned)**	**Primary Predicate Device K183702**	**Conclusion**
Device name:	**Armory Motion and Armory Force**	**Polar Care Wave**	
Submitter:	Pain Management Technologies	Breg, Inc.	
Indications for use:	The Armory Motion is a prescription device that combines cold and compression therapy and is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain for which cold and compression are indicated. Armory Motion is intended to be used by a licensed health care professional in rehabilitation facilities, outpatient clinics, athletic training settings, and home settings.	The Breg is a prescription device intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain where cold and compression are indicated. It is intended to be used by or on the order of licensed healthcare professionals in hospitals, outpatient clinics, athletic training settings, or home settings.	Substantially equivalent
OTC use	Prescription	Prescription	Substantially Equivalent.
Classification Number	21 CFR 820.5650 21 CFR 890.5720	21 CFR 820.5650 21 CFR 890.5720	Substantially Equivalent.
Classification Name	Powered Inflatable Tube Massager; Water Circulating hot or cold pack	Powered Inflatable Tube Massager; Water Circulating hot or cold pack	Substantially Equivalent.
Regulatory Class	II	II	Substantially Equivalent.

510(K)No.:	**(to be assigned)**	**Primary Predicate Device K183702**	**Conclusion**
Device name:	**Armory Motion and Armory Force**	**Polar Care Wave**	
Product Code	IRP,ILO	IRP, ILO	Substantially Equivalent.
Classification Panel	Neurological and Physical Medicine;	Neurological and Physical Medicine;	Substantially Equivalent.
Therapy	Cold and Compression Work together or independently	Cold and Compression Work together or independently	Substantially Equivalent.
Therapy modes	Manually adjustable mode – allows the user to adjust cold and two compression settings.	Manually adjustable mode – allows the user to adjust cold and two compression settings.	Substantially Equivalent.
Compression Setting	Available in two levels Low (0-25 mm Hg) Regular (0-50 mm Hg)	Available in two levels Low (0-25 mm Hg) Regular (0-50 mm Hg)	Substantially Equivalent
Types of Pads	Various anatomical pads: Knee, Shoulder, Back, calf, Universal/joint, Foot/Ankle	Various anatomical pads: Knee, Shoulder, Back, Hip, Universal, Foot/Ankle	Substantially Equivalent
Therapy Temperature Range	45°F-60°F Cold	45°F-60°F	Substantially Equivalent
Operating fluid and cooling agent	Tap water and Ice	Tap water and Ice	Substantially Equivalent
Single User and sterility	Single user and non-sterile	Single user and non-sterile	Substantially Equivalent

510(K)No.:	(to be assigned)	Primary Predicate Device K183702	Conclusion
Device name:	**Armory Motion and Armory Force**	**Polar Care Wave**	
Line Voltage / Frequency	Rechargeable battery and 100-240 VAC 50/60 HZ	100-240 VAC 50/60 HZ	Substantially Equivalent.
Treatment times	15, 20, 30, 45; compression stops at 30 min max	Continuous, until turn-off byuser	Substantially Equivalent
Cooling on/off times	15, 20, 30, 45	. Continuous, until turn-off byuser	Substantially Equivalent
Pressure Mode	Two compression modes and one cold therapy mode	Three	Substantially Equivalent
Power Supply	- 3.7V rechargeable Li-ion Polymer Battery - Power Adapter	Power Adapter	Substantially Equivalent.

Both the new device Armory Motion and the predicate device Breg Polar Care Wave (K183702) provide continuous intermittent pneumatic massage using inflatable garments.The new device Armory Motion and predicate device have the same indications for use, both operate within the similar parameters and performance specifications. The new device Armory Motion and predicate device use the similar inflation pressures and cycle times.

Furthermore, a subtle difference between the new device Armory Motion and the predicate device is in their respective alarm function. The new device has a malfunction overpressure safety alarm: any time the pressure in the air chamber exceeds 100mmHg, it will stop working and deflate immediately. The device panel shall sleep with the red warning sign on and flash for 20 seconds.

Substantial Equivalence None of the performance or technological differences between the Armory Motion Device and the predicate device raise any new issues of safety and effectivenes.

CONCLUSION:
The data, and information provided in this submission, support the conclusion that the Armory Motion Safety features are Substantially Equivalent to those of Breg Polar Care Wave (K183702). No special safety features have been shown to be necessary for home use without instruction.

VII Performance Tests:

FDA recognition No.	Standard Title
19-4	ANSI AAMI 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 60601-1:2005, MOD)
19-8	IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
19-14	IEC 60601-1-11 Edition 2.0 2015-01 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
5-40	ISO 14971: Second Edition 2007-03-01 Medical devices- Application of Risk Management To Medical Devices.
5-89	IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
13-79	IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes
2-220	ANSI AAMI ISO 10993-1:2009/(R)2013 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

V Clinical Testing

No formal clinical testing was performed on the Armory Motion. The clinical testing is not applicable in this submission.

IX Conclusion:

- The new device Armory Motion has the same technological characteristics and intended uses as the predicate deivce Breg Polar Care Wave (K183702); and
- The labelling of the new device Armory Motion is concordant with the predicate device and FDA requirements; and
- The information submitted to the FDA for the new device Armory Motion does not raise new questions about safety or effectiveness and demonstrates with reasonable assurance based on established controls that the device is at least as safe and effective as a legally marketed device.

Therefore, the new device Armory Motion is substantially equivalent to the predicate device and differences between the devices do not raise any new questions about safety and effectiveness.