March 1, 2019

Breg Inc.
Monique Zamora
Manager, Quality Engineering
2885 Locker Ave. East
Carlsbad, California 92010

Re: K183702
Trade/Device Name: Polar Care Wave
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP, ILO
Dated: December 28, 2018
Received: December 31, 2018

Dear Monique Zamora:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Vivek J. Pinto -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183702

Device Name
Polar Care Wave

Indications for Use *(Describe)*
The Polar Care Wave System is 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.

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.

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"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

Date Prepared: February 27, 2019

Submitter: Breg, Inc.
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Contact person: Monique Zamora
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DEVICE INFORMATION:

Proprietary Name:	Polar Care Wave™
Common Name:	Cold and Compression Therapy
Regulatory Common:	Powered inflatable tube massager (21 CFR 820.5650) Water circulating hot or cold pack (21 CFR 890.5720)
Device Product Code:	IRP, ILO
Classification:	Class II (510(k) required)
Classification Panel:	Physical Medicine

PREDICATE DEVICE:

Predicate	510(k)	Device Name	Company
Primary	K072620	Game Ready Classic System	CoolSystems, Inc.
Secondary	K171685	Med4 Elite	CoolSystems, Inc.

PRODUCT DESCRIPTION:

The Polar Care Wave system is an AC powered, software controlled, multimodality system. The device is intended for application of external cold therapy and intermittent pneumatic compression therapy to be used by, or on the order of, licensed healthcare professionals in hospitals, outpatient clinics, athletic training settings, or home settings. The device features a multi-setting cold therapy module and multi-setting compression therapy module which can be run simultaneously or independently.

The device contains three key parts: A cold-compression pad with connector, 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 device is intended to be used with Breg Cold-Compression pads only, which are designed for specific application sites. The cold-compression pads are available for the core regions; back, shoulder, hip, and knee and for the extremity region, foot/ankle. 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.

INDICATIONS FOR USE:
The Polar Care Wave System is 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.

COMPARISON TO PREDICATE:

The following table compares the characteristics of the Polar Care Wave and the predicate devices.

Feature	Polar Care Wave	Game Ready, K072620	Med4 Elite, K171685	Difference / Implication
Product Code Regulation Number	**IRP** Powered inflatable tube massager (21 CFR 820.5650) **ILO** Water circulating hot or cold pack (21 CFR 890.5720)	**IRP** Powered inflatable tube massager (21 CFR 820.5650) **ILO** Water circulating hot or cold pack (21 CFR 890.5720)	**IRP** Powered inflatable tube massager (21 CFR 820.5650) **ILO** Water circulating hot or cold pack (21 CFR 890.5720)	Substantially Equivalent
Regulatory Class	II	II	II	Substantially Equivalent
Intended Use	The Polar Care Wave system is intended to treat post-surgical and acute injuries to help 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.	The Game Ready Classic System is 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.	The Med4 Elite combines cold, heat, contrast and compression therapies. It is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain where cold and compression are indicated. It is intended to treat post traumatic and post-surgical medical and/or surgical conditions for which localized thermal therapy (hot or cold or contrast) are indicated. It is intended to be used by or on the order of licensed health care professionals in rehabilitation facilities, outpatient clinics and athletic training settings.	The Polar Care Wave and the primary predicate device (Game Ready Classic System) Intended Use are substantially equivalent. The Polar Care Wave and the secondary predicate device (Med4 Elite) have similar intended uses, the difference is that the Polar Care Wave does not provide heat or contrast therapy.

Feature	Polar Care Wave	Game Ready, K072620	Med4 Elite, K171685	Difference / Implication
Indications for Use	The Polar Care Wave product is intended for the application of external cold and compression therapy to temporarily reduce pain, swelling, and/or inflammation resulting from injury or surgery. The use of cold and compression therapy has been shown to reduce opioid consumption following surgical procedures. It is intended for use by or on the order of licensed healthcare professionals in hospitals, outpatient clinics, athletic training settings, and/or home settings.	The Game Ready Classic System is 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.	The Med4 Elite combines cold, heat, contrast and compression therapies. It is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain where cold and compression are indicated. It is intended to treat post traumatic and post-surgical medical and/or surgical conditions for which localized thermal therapy (hot or cold or contrast) are indicated. It is intended to be used by or on the order of licensed health care professionals in rehabilitation facilities, outpatient clinics and athletic training settings.	The Polar Care Wave and the primary predicate device (Game Ready Classic System) Indications For Use are substantially equivalent. The Polar Care Wave and the secondary predicate device (Med4 Elite) have similar Indications For Use, the difference is that the Polar Care Wave does not provide heat or contrast therapy.
Intended Users	Health Care Professionals and lay users (under prescription).	Health Care Professionals and lay users (under prescription)	Health Care Professionals only (under prescription)	All three devices are prescription only. The secondary predicate is only used by Health Care Professionals.
Intended Use Environment	Intended for indoor use	Intended for indoor use	Intended for indoor use	Substantially Equivalent
Therapy	Cold and Compression Work together or independently	Cold and Compression Work together or independently	Cold, Heat, Contrast and Compression	All three devices provide cold and compression therapy. The secondary predicate provides heat and contrast therapy.

Feature	Polar Care Wave	Game Ready, K072620	Med4 Elite, K171685	Difference / Implication
Therapy sessions	Manual mode – allows the user to adjust cold and compression settings as directed by a Health Care Professional.	Manual mode – allows the user to adjust treatment time and pressure settings. Program mode – allows the user to choose one of six treatment programs that provide therapy for a set time at a specific pressure setting.	Program mode – allows the user to choose treatment programs and therapy times.	The Polar Care Wave and the primary predicate contain a manual mode for temperature and compression therapies that are controlled by the user.
Types of Pads	Various anatomical pads: Knee, Shoulder, Back, Hip, Universal, Foot/Ankle	Various anatomical pads: Straight knee, Articulated Knee, Elbow, Ankle, Shoulder, Back, Hip-Groin, Hand-Wrist	Various anatomical pads: Straight knee, Articulated Knee, Elbow, Ankle, Shoulder, Back, Hip-Groin, Hand-Wrist	Substantially Equivalent
Compression Setting	Available in two levels Low (0-25 mm Hg) Regular (0-50 mm Hg)	Available in three levels Low (5-15 mm Hg) Medium (5-50 mm Hg) High (5-75 mm Hg)	Available in four levels Low (5-15 mm Hg) Medium-Low (5-30 mm Hg) Medium (5-50 mm Hg) High (5-75 mm Hg)	The Polar Care Wave and the predicate devices provide intermittent compression with multiple settings. The Polar Care Wave high pressure is within the pressure range of the predicate devices. The low pressure for the Polar Care Wave is less than the predicate devices, there is no safety or effectiveness issues since this represents the minimum pressure during a deflation cycle.

Feature	Polar Care Wave	Game Ready, K072620	Med4 Elite, K171685	Difference / Implication
Cold Therapy	Available without and with compression (Low and Regular)	Available without and with compression (Low, Medium-low, Medium, High)	Available without and with compression (Low, medium High)	Substantially Equivalent
Therapy Temperature Range	45°F-60°F	34°F-50°F	38°F-60°F (+/- 4°F accuracy)	The Polar Care Wave temperature range is within the temperature range of the secondary predicate and the low end of the range is within the primary predicate.
Heat Therapy	Not Available	Not Available	Available without and with compression (Low)	The Polar Care Wave and the primary predicate are substantially equivalent. The secondary predicate provides heat therapy.
User Interface	Keypad with indicator lights	Button, dial with display	Touch Screen	The Polar Care Wave uses a keypad for user interaction as compared to the primary predicate dial control and the secondary predicate touch screen. The different control mechanisms do not affect safety and effectiveness.
Operating Fluid	Tap Water	Tap Water	Distilled Water	Substantially Equivalent

Feature	Polar Care Wave	Game Ready, K072620	Med4 Elite, K171685	Difference / Implication
Water Cooling Source	Ice	Ice	Vapor Compression	Substantially Equivalent
Single User Cold Compression Pad	Yes	Yes	Yes	Substantially Equivalent
Cold Compression Pad Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Substantially Equivalent
Line Voltage / Frequency	100-240 VAC 50/60 HZ	100-240 VAC 50/60 HZ	100-240 VAC 50/60 HZ	Substantially Equivalent

Substantial Equivalence
None of the performance or technological differences between the Polar Care Wave and the predicates raise any new issues of safety and effectiveness.

Performance Testing
The Polar Care Wave System has been subjected to design verification and validation testing. These tests verified and validated the proper operation of the system. The Polar Care Wave device has been found to be adequately safe and effective for the intended users, its intended uses, and use environment. The labeling materials have been found to be easy to use and understandable to the intended users.

Software
The software in the Polar Care Wave system has been validated and demonstrated to be safe and effective for its intended use.

Electrical Safety and Electromagnetic Compatibility
The Polar Care Wave system is certified to the medical electrical safety standards of IEC 60601 3rd edition, including the ANSI/AAMI/ ES60601 collateral standards, 60601-1-6 and 60601-1-11. The system also complies with the EMC standard, IEC 60601-1-2 4th edition.

Conclusion
The data and information provided in this submission, support the conclusion that the Breg Polar Care Wave is substantially equivalent to its predicate devices with respect to indications for use and technological characteristics associated cold and compression.