May 1, 2024

JKH Health Co., Ltd.
% Bill Quanqin Dai
Managing Member
JKH USA LLC
14271 Jeffrey Road #246
Irvine, CA 92620

Re: K240986
Trade/Device Name: Cold Compression
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: Class II
Product Code: IRP, ILO
Dated: February 22, 2024
Received: April 10, 2024

Dear Bill Dai:

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.

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 Rehabilitation 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)*

K240986

Device Name

Cold Compression

Indications for Use *(Describe)*

Cold Compression is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain for which cold and compression are indicated.

Cold Compression is intended to be used by or on the order of licensed healthcare professionals in rehabilitation facilities/hospitals, 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.

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510(k) Summary

1. Submitter's Information

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E-mail: sales@JKHhealth.com
Date of Preparation: 4/09/2024

2. Subject Device

Trade/Device Name: Cold Compression
Common Name: Powered Inflatable Tube Massager; Hot or Cold, Water Circulating Pack
Regulation Medical Specialty: Physical Medicine
Review Panel: Physical Medicine
Product Code: IRP, ILO
Regulation Number: 21 CFR 890.5650, 21 CFR 890.5720
Device Class: II
Use: Prescription

Predicate device

Primary Predicate Device: Cold/Hot Compression
510(k) Number: K223541
Clearance Date: October 27, 2023
Submitter: JKH Health Co., Ltd.

Predicate Device: Polar Care Wave
510(k) Number: K183702
Clearance Date: March 1, 2019
Submitter: Breg Inc.

3. Description of Subject Device

The subject device is an AC powered, software-controlled multimodality device, and is intended to be used by or on the order of licensed healthcare professionals in rehabilitation facilities/hospitals, outpatient clinics, athletic training settings, and home settings.

The subject device features cold therapy and compression therapy. Cold Compression is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain for which cold and compression are indicated.

The device has a power/time button, temperature adjustment button, pressure setting button; Patients can adjust the temperature, compression pressure, and duration of treatment according to their needs.

The device has a bucket body and a lid. The ice and water can be added by opening the lid, and the loading level of the ice and water can be indicated/seen.

The subject device and its packaging/clothing are clean and non-sterile. A connecting tube is used to

connect the subject device to the wrap/pad. The wraps come with a variety of reusable cold treatment inflators for cold and compression treatment of the universal, back, shoulder, ankle/foot, hip, and knee.

4. Indications for Use

Cold Compression is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain for which cold and compression are indicated.

Cold Compression is intended to be used by or on the order of licensed healthcare professionals in rehabilitation facilities/hospitals, outpatient clinics, athletic training settings, and home settings.

5. Summary of Substantial Equivalence

The comparison Table 1 summarizes the detailed comparison between the subject device and the predicate device, indicating the technical characteristics, specifications, and intended use of the subject device are substantially equivalent to those of the predicate device.

Table 1. Comparison between the subject device and the predicate device

	Subject Device	**Primary Predicate Device**	**Predicate Device**	**Equivalence**
510(k) Number	K240986	K223541	K183702	N/A
Submitter	JKH Health Co., Ltd.	JKH Health Co., Ltd.	Breg Inc.	N/A
Device Name/Model	Cold Compression	Cold/Hot Compression	Polar Care Wave	N/A
Product Code Regulation Number	IRP and ILO	IRP, ILO, and JOW	IRP and ILO	The subject device has the product codes covered by the primary predicate device, and also identical to the predicate device.
Indications for Use	Cold Compression is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain for which cold and compression are indicated. Cold Compression is intended to be used by or on the order of licensed healthcare professionals in rehabilitation facilities/hospitals, outpatient clinics, athletic training settings, and home settings.	Cold/Hot Compression combines cold, heat, contrast, and compression therapy. It is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain for which cold and compression are indicated. It is intended to treat post traumatic and postsurgical medical and/or surgical conditions for which localized thermal therapy (hot or cold) are indicated. Cold/Hot Compression also provide DVT therapy. It is intended to reduce the risk of the formation of deep venous thrombosis (DVT) by aiding blood flow back to the heart via lower extremity limb compression. Cold/Hot Compression is intended to be used by, or on the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, athletic training settings, and home settings.	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.	The subject device has the Indications for Use covered by the primary predicate device, and also substantially equivalent to the predicate device.
Intended Users	Health Care Professionals and	Health Care Professionals and	Health Care Professionals and	Identical

	lay users (under prescription)	lay users (under prescription)	lay users (under prescription)	
Age range of the target population	Adult; children and the elderly should only use the product under direct supervision of a medical professional	Adult; children and the elderly should only use the product under direct supervision of a medical professional	Adult; children and the elderly should only use the product under direct supervision of a medical professional	Identical
Prescription or OTC	Prescription	Prescription	Prescription	Identical
Power Source(s)	100-240 VAC, 50/60 Hz	100-240 VAC, 50/60 Hz	100-240 VAC, 50/60 Hz	Identical
Compliance with Voluntary Standards?	Yes	Yes	Yes	Identical
Electrical Safety Mechanical Safety Chemical Safety Thermal Safety Radiation Safety?	Yes	Yes	Yes	Identical
Therapy	Cold and Compression Work together or independently	Cold, Heat, Contrast and Compression	Cold and Compression Work together or independently	The subject device has the therapy covered by the primary predicate device, and also identical to the predicate device. The difference between the subject device and the primary predicate device is the former does not provide heat or contrast therapy.
Cold Therapy	45°F - 55°F	Default: 50°F Custom: 41°F–55°F Default, continuous: 50°F Custom, continuous: 41°F–50°F	45°F – 60°F	Equivalent Note 1
Heat Therapy	Not Available	Default: 105°F Custom: 105°F–109°F Default, continuous: 105°F Custom, continuous: 105°F-109°F	Not Available	Identical to the predicate device. The difference between the subject device and the primary predicate device is the former does not provide heat or contrast therapy.
Compression Setting	0 - 60 mmHg	Compression Therapy Alternate mode：15 -75 mm Hg Compression Therapy Continuous mode：15 -75 mm Hg	Available in two levels Low (0-25 mmHg) Regular (0-50 mmHg)	Equivalent Note 2
Reservoir Fluid Capacity	620 mL	350 mL	Not Available	Different, but it will not raise any new issue of the safety or effectiveness.
Recommended Coolant	Tap Water	90% Distilled Water, 10% Isopropyl Alcohol	Tap Water	Identical to the predicate device. The difference between the subject device and the primary predicate device is the former does not provide heat or contrast therapy.
Water Cooling Source	Ice	Vapor compression	Ice	Identical to the predicate device. The difference between the subject device and the primary predicate device is the former does not provide heat or contrast therapy.
User Interface	Keypad with indicator lights or LCD screen	Touch Screen	Keypad with indicator lights	Different from the primary predicate

				device and similar to the predicate device. It will not raise any new issue of the safety or effectiveness.
Dimensions	L235xW235xH280mm	L295xW285xH295 mm	Not Available	Different. The difference of dimensions does not change the product performance or parameters, which will not raise any new issue of the safety or effectiveness.
Weight Approx.	2.4kg	8.2kg	Not Available	Different. The difference of weight does not change the product performance or parameters, which will not raise any new issue of the safety or effectiveness.
Types of Garments	Various anatomical thermal garments for: Back, Elbow/Universal, Shoulder, Knee, Ankle, Hip.	Various anatomical thermal garments for: Back, Elbow, Shoulder, Knee, Ankle, Hip. DVT Garments: Calf and Foot	Various anatomical thermal garments for: Back, Universal, Shoulder, Knee, Foot/Ankle, Hip.	The subject device has the garments covered by the primary predicate device, and also substantially equivalent to the predicate device.
Biocompatibility of Patient Contacting Material	Biocompatible	Biocompatible	Biocompatible	Identical
Sterile/Non-Sterile	Non-sterile	Non-sterile	Non-sterile	Identical
Cleaning Disinfection Validation of Labeling	Yes	Yes	Yes	Identical
Operational and Environmental Conditions	- Normal working ambient temperature: 5~40°C - Normal working ambient humidity: 15%～90% - Store and transport ambient temperature: -25~70°C - Store and transport ambient humidity: 10~90% - Atmospheric pressure: 70~106kPa	- Normal working ambient temperature: 16~27°C - Normal working ambient humidity: Below 60% - Store and transport ambient temperature: 1~50°C - Store and transport ambient humidity: Below 60% - Atmospheric pressure: 70~106kPa	- Normal working ambient temperature: 5~40°C - Normal working ambient humidity: 15%～90% - Store and transport ambient temperature: -25~70°C - Store and transport ambient humidity: 10~90% - Atmospheric pressure: 70~106kPa	Identical to the predicate device. The difference between the subject device and the primary predicate device is the former does not provide heat or contrast therapy.

Equivalent Note 1: The temperature range of cold therapy for the subject device is within that of the primary predicate device and the predicate device. In addition, the temperature of cold therapy for both the subject and predicate devices can be adjusted and determined by the health care professionals or on the order of health care professionals. Therefore, the temperature difference of cold therapy between the subject and predicate devices is insignificant. Such a difference between the subject and predicate devices does not raise any new issues of safety or effectiveness.

Equivalent Note 2: The pressure range of compression therapy for the subject device is within that of the primary predicate device, and is slightly higher than that of the predicate device. In addition, the pressure level can be adjusted and determined for both the subject device and the predicate device by the health care professionals or on the order of health care professionals. Therefore, the difference of compression pressure between the subject and predicate devices is insignificant. Such a difference between the subject device and the predicate device does not raise any new issues of safety or effectiveness.

6. Substantial Equivalence

As discussed above and shown in the above table, the subject device in this submission has the identical or similar performance and parameter to the predicate device. And the differences between the subject device and the predicate device do not raise any new issues of safety or effectiveness. Also, the differences between the subject and predicate devices do not affect the intended use or alter the fundamental technology of the device. There are no new safety or effectiveness issues concerning the subject device, which offers substantially equivalent technical specifications, features, intended use, safety, and effectiveness to the predicate device.

Identical to the predicate device, the subject device has multiple audible and visual safety alarms built into the system, including low pressure alarm and low battery alarm. The microprocessor and pump units can be powered by the internal rechargeable battery, or can be connected to the main AC power line (through the battery charger / AC adaptor). The skin contact components and materials of the subject device are identical to those of the predicate device in formulation, suppliers, processing, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.). Therefore, there is no issue or concern of biocompatibility.

7. Non-Clinical Tests Performed

Non-clinical tests were performed on the subject device in order to validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility.

(a) IEC 60601-1 "Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1)".

(b) IEC 60601-1-2 "Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral standard: Electromagnetic Compatibility - Requirements and Tests".

8. Clinical Testing

Clinical testing was not needed in support of this 510(k) application.

9. Conclusion

The tests and comparison performed demonstrate the subject device is substantially equivalent to the predicate device. Therefore, the subject device is as safe and effective as the predicate device that has been legally marketed in the United States.