October 27, 2023

JKH Health Co., Ltd.
Bill Quanqin Dai, Ph.D.
Official Correspondent
14271 Jeffrey Rd. #246
Irvine, California 92620

Re: K223541
Trade/Device Name: Cold/Hot Compression
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP, ILO, JOW
Dated: September 26, 2023
Received: September 28, 2023

Dear Dr. 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,

Heather L. Dean -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223541

Device Name
Cold/Hot Compression

Indications for Use *(Describe)*
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 post-surgical 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.

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.

510(k) Summary

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter's Information

Submitter: JKH Health Co., Ltd.
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Email: sales@JKHhealth.com
Date of Preparation: October 24, 2022

2. Subject Device

Trade/Device Name: Cold/Hot Compression
Regulation Description: Name: Powered Inflatable Tube Massager; Hot Or Cold, Water Circulating Pack; Compressible Limb Sleeve
Regulation Medical Specialty: Physical Medicine, Cardiovascular
Review Panel: Physical Medicine, Cardiovascular
Product Code: IRP, ILO, JOW
Regulation Number: 21 CFR 890.5650, 21 CFR 890.5720, 21 CFR 870.5800
Device Class: II
Use: Prescription

3. Predicate device

Predicate Device: Therm-X
510(k) Number: K193550
Clearance Date: February 28, 2020
Submitter: Zenith Technical Innovations, LLC

Reference Device: NanoTherm and VascuTherm Systems
510(k) Number: K061866
Clearance Date: August 22, 2006
Submitter: ThermoTek, Inc.

4. Description of Subject Device

The subject device is a prescriptive device, which combines cold/hot therapy and air compression. 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 post-surgical medical and/or surgical conditions for which localized thermal therapy (hot or cold) are indicated. 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.

The subject device comes with the thermal-therapy wraps and the DVT wraps. The thermal-therapy wrap is nylon fabric on one side and velvet cloth on the other side; the DVT wrap is velvet on both sides. To avoid any potential adverse skin reactions such as redness, irritation, and cold/hot injury, the sock/clothing should be worn by the patient prior to use.

The subject device includes a main device and an optional DVT device, and has a limited shelf life of 3 years, based on the charge retention characteristics of the device's battery. Please find the detailed storage condition and maintenance in the user manual.

5. Indications for Use

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 post-surgical 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.

6. 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	**Predicate Device**	**Reference Device**	**Equivalence**
510(k) Number	K223541	K193550	K061866	N/A
Submitter	JKH Health Co., Ltd.	Zenith Technical Innovations, LLC	ThermoTek, Inc.	N/A
Device Name/Model	Cold/Hot Compression	Therm-X	VascuTherm	N/A
Indications for Use	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 post-surgical 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	Therm-X (Therm-X Home and Therm-X AT) combines cold, heat, contrast, and compression therapy. Therm-X 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 post-surgical medical and/or surgical conditions for which localized thermal therapy (hot or cold) are indicated. Therm-X Home systems also provide DVT therapy. Therm-X Home systems with DVT therapy are 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.	Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema. Reduction of edema associated with soft tissue injuries such as bums, postoperative edema, and ligament sprains. Localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions. Decrease the risk of deep venous thrombosis (DVT). Aids the blood flow back to the heart.	Identical

	the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, athletic training settings, and home settings.	Therm-X (Therm-X Home and Therm-X AT) 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.	Treat and assist healing of cutaneous ulceration (wounds), reduce would healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications.	
Intended Users	Health Care Professionals and lay users (under prescription)	Health Care Professionals and lay users (under prescription)	Health Care Professionals and lay users (under prescription)	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
Cold Therapy	Default: 50°F Custom: 41°F–55°F Default, continuous: 50°F Custom, continuous: 41°F – 50°F	Default: 34°F, 45°F, 55°F Custom: 34°F – 55°F Default, continuous: 40°F, 45°F, 50°F Custom, continuous: 40°F – 50°F	Default: 49°F Custom: 43°F–49°F Default, continuous: 49°F Custom, continuous: 43°F – 49°F	Equivalent Note 1
Heat Therapy	Default: 105°F Custom: 105°F–109°F Default, continuous: 105°F Custom, continuous: 105°F – 109°F	Default: 105°F, 107°F, 110°F Custom: 105°F –110°F Default, continuous: 105°F, 107°F Custom, continuous: 105°F – 107°F	Default: 105°F Custom: 100°F–105°F Default, continuous: 105°F Custom, continuous: 100°F – 105°F	Equivalent Note 2
Edema Pressure Levels	Compression Therapy Alternate mode：15 -75 mm Hg Compression Therapy Continuous mode：15 -75 mm Hg	Available in four levels: Lite (5 mm Hg) Low (20 mm Hg) Medium (45 mm Hg) High (70 mm Hg) For continuous treatment, available in three levels: Low (20 mm Hg) Medium (45 mm Hg) High (70 mm Hg)	Compression Therapy 3 Settings: Low (15 mm Hg) Medium (30 mm Hg) High (50 mm Hg)	Equivalent Note 3
Static or Intermittent Pressure	Both	Both	Intermittent Pressure available	Identical
DVT Only	Available	Available for Therm-X Home Model	Available	Identical
DVT Pressure	Calf: 55 mmHg Foot: 130 mmHg	Calf: 50 – 70 mmHg Foot: 90 – 130 mmHg	Calf: 45 mmHg Foot: 100 mmHg	Equivalent Note 4
Cycle Length (for Heat, Cold, And Compression)	Default: 30 minutes Custom: 1 – 60 minutes	Default: 10 or 20 minutes Custom: 3 – 40 minutes Continuous: 10 – 40 minutes active, 30-60 minutes rest	Default: 90 minutes	Equivalent Note 5
Contrast Therapy	Heat: 105°F Cold: 49°F	Heat: 105°F Cold: 38°F	Heat: 105°F Cold: 49°F	Equivalent Note 6
Cycle Length (for Contrast Therapy)	Heat: 10 minutes Cold: 20 minutes	Heat: 3-10 minutes Cold: 3-10 minutes Total treatment: 6-60 minutes	Heat: 10 minutes Cold: 20 minutes	Equivalent Note 7
DVT Cycle Length	No specified time interval. DVT can be stopped at any time by the user.	No specified time interval. DVT can be stopped at any time by the user.	No specified time interval. DVT can be stopped at any time by the user.	Identical
Edema Compression and DVT Compression at the same time	Available Edema Compression must be combined with cold, heat, or contrast therapy	Available Edema Compression (Lite, Low, Medium, High) must be	Available Edema Compression (Lite, Low, Medium, High) must be	Identical

		combined with cold, heat, or contrast therapy	combined with cold, heat, or contrast therapy	
Inflation and Deflation	Inflation: Up to 120 seconds Deflation: Up to 30 seconds	Inflation: Up to 120 seconds Deflation: Up to 30 seconds	Inflation: Up to 120 seconds Deflation: Up to 30 seconds	Identical
Store Cycle Usage Data	Available	Available	Available	Identical
Chilling Mechanism	Thermoelectric	Thermoelectric	Thermoelectric	Identical
Heating Mechanism	Thermoelectric	Thermoelectric	Thermoelectric	Identical
Reservoir Fluid Capacity	350 mL	650 mL	300mL	Equivalent Note 8
Recommended Coolant	90% Distilled Water, 10% Isopropyl Alcohol	90% Distilled Water, 10% Isopropyl Alcohol	90% Distilled Water, 10% Isopropyl Alcohol	Identical
User Interface	Touch Screen	Touch Screen	Touch Screen	
Dimensions	L295xW285xH295 mm	15" L x 10.5" W x 9" H	L170xW170xH300 mm	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.	8.2kg	15 lbs. when full of coolant	8.7kg	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.
Operating Temperature	60°F – 80°F (16°C – 27°C)	60°F – 80°F (16°C – 27°C)	60°F – 80°F (16°C – 27°C)	Identical
Storage Temperature	33°F – 122°F (1°C - 50°C)	33°F – 122°F (1°C - 50°C)	33°F – 122°F (1°C - 50°C)	Identical
Operating Humidity	Below 60% Noncondensing	Below 60% Noncondensing	Below 60% Noncondensing	Identical
Storage Humidity	Below 60% Noncondensing	Below 60% Noncondensing	Below 60% Noncondensing	Identical
Operating Atmospheric Pressure and Altitude	700 hPa – 1060 hPa (corresponds to a max. elevation of 9,842 ft. 6 in (3000 m))	700 hPa – 1060 hPa (corresponds to a max. elevation of 9,842 ft. 6 in (3000 m))	700 hPa – 1060 hPa (corresponds to a max. elevation of 9,842 ft. 6 in (3000 m))	Identical
Types of Garments	Various anatomical thermal garments for: Back, Elbow, Shoulder, Knee, Ankle, Hip. DVT Garments: Calf and Foot	Various anatomical thermal garments for: Back, Elbow, Shoulder, Knee, Ankle, Hip. DVT Garments: Calf and Foot	Various anatomical thermal garments for: Back, Elbow, Shoulder, Knee, Ankle, Hip. DVT Garments: Calf and Foot	Identical
Patient Contacting Material	Thermal garment – nylon fabric on one side and velvet cloth on the other side DVT garment – velvet on both sides	Thermal garment, reusable (multi-patient) – 30 denier nylon coated in urethane Thermal garment, disposable (single-patient) – 200 denier nylon coated in urethane DVT garment – 200 denier nylon coated in urethane	Thermal garment– 200 denier nylon oxford DVT garment– DuPont Softesse Medical Fabric (non-latex, non-woven)	Different. To avoid any potential adverse skin reactions such as redness, irritation, and cold/hot injury, the sock/clothing should be worn by the patient prior to use.
Sterile/Non-Sterile	Non-sterile	Non-sterile	Non-sterile	Identical
Cleaning Disinfection Validation of Labeling	Yes	Yes	Yes	Identical

Equivalent Note 1: The cold therapy of the subject device has the default temperature of 50°F, which is within the range of the Predicate device and is almost the same as that of the Reference device. Similarly, the temperature range of cold therapy for the subject device is either within that of the Predicate device or almost the same as that of the Reference device. And the lowest temperature of cold therapy for the subject device (41 ^{o}F) is between that of the Predicate device (34 or 40 ^{o}F) and that of the Reference device (43 ^{o}F). 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, which at least is similar to the case in K181149. Such a difference between the subject and predicate devices does not raise any new issues of safety or effectiveness.

Equivalent Note 2: The heat therapy of the subject device has the default temperature of 105°F, which is within the range of the Predicate device and is the same as that of the Reference device. Similarly, the subject device has the temperature range of heat therapy almost the same as the range of both the Predicate device and the Reference device. And the highest temperature of heat therapy for the subject device (109 ^{o}F) is between that of the Predicate device (110 ^{o}F) and that of the Reference device (105 ^{o}F). In addition, the temperature of heat 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 heat therapy between the subject and predicate devices is insignificant, which at least is similar to the case in K181149. Such a difference between the subject and predicate devices does not raise any new issues of safety or effectiveness.

Equivalent Note 3: The lowest edema pressure level of the subject device (15 mmHg) is within that of the Predicate device (5 or 20 mmHg), and is also the same as that of the Reference device (15 mmHg). The highest edema pressure level of the subject device (75 mmHg) is slightly higher than that of both the Predicate device (70 mmHg) and the Reference device (50 mmHg). In addition, the edema 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 edema pressure between the subject and predicate devices is insignificant, which at least is similar to the case in K181149. Such a difference between the subject device and the predicate device does not raise any new issues of safety or effectiveness.

Equivalent Note 4: The DVT pressure of the subject device on the calf is 55mmHg, which is within the range of the Predicate device (50-70 mmHg) and is slightly higher than that of the Reference device (45 mmHg). Similarly, the DVT pressure of the subject device on the foot (130 mmHg) is within the range of the Predicate device (90-130 mmHg) and is somewhat higher than that of the Reference device (100 mmHg). Therefore, the difference of DVT pressure between the subject and predicate devices is insignificant, which at least is similar to the case in K181149. Such a difference between the subject device and the predicate device does not raise any new issues of safety or effectiveness.

Equivalent Note 5: The longest cycle length of the subject device (60 minutes) is the same as or longer than that of the Predicate device (40 or 60 minutes), but it is shorter than that of the Reference device (90 minutes). In addition, the cycle length can be adjusted and determined by the health care professionals or on the order of health care professionals. Therefore, the difference of cycle length between the subject and predicate devices is insignificant, which at least is similar to the case in K181149. Such a difference between the subject device and the predicate device does not affect the safety or effectiveness.

Equivalent Note 6: The contrast therapy of the subject device is slightly different from that of the Predicate device, and is exactly the same as that of the Reference device. Therefore, such a difference

between the subject device and the predicate device does not raise any new issues of safety or effectiveness.

Equivalent Note 7: The cycle length of the contrast therapy for the subject device is slightly different from the Predicate device, while it is exactly the same between the subject device and the Reference device. Therefore, such a difference between the subject device and the predicate device does not affect the safety or effectiveness.

Equivalent Note 8: The reservoir fluid capacity of the subject device is smaller than that of the Predicate device, while it is larger than that of that of the Reference device. Therefore, the different reservoir fluid capacity between the subject device and the predicate device does not raise any new issues of safety or effectiveness.

7. Substantial Equivalence

As discussed above and shown in the above Table 1, the subject device in this submission has the identical or equivalent 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.

As demonstrated, 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.

8. 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) ANSI AAMI ES60601-1 "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".

In addition to the compliance of voluntary standards, bench performance tests for the user interface and display performance, operation time, the cooling temperature, heating temperature, pressure test, low pressure alarm, inflation-deflation cycle times, and leakage and burst testing were conducted in support of substantial equivalence, and the verification of software used in the subject device has been carried out according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

Due to the requirement that clothing be worn beneath the wraps by the user, the biocompatibility of the device materials have not been verified by FDA.

9. Clinical Testing

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

10. Conclusion

The test 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.