October 24, 2025

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

Re: K253150
Trade/Device Name: Cryon-X Cold Compression
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP, ILO, JOW
Dated: September 10, 2025
Received: September 25, 2025

Dear Bill Quanqin 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.

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

Tushar Bansal, PhD
Acting 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

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.*

510(k) Number *(if known)*
K253150

Device Name
Cryon-X Cold Compression

Indications for Use *(Describe)*

Cryon-X Pro

The private-label Cryon-X Pro device 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) is indicated.

The device may optionally provide DVT therapy, 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.

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

Cryon-X One

The private-label Cryon-X One device combines cold 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 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 (K253150)**

## 1. Submitter's Information

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Tel: +86-755-27926589
E-mail: sales@JKHhealth.com
Date of Preparation: 22/09/2025

## 2. Subject Device

Trade/Device Name: Cryon-X Cold Compression
Common 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

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

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

Predicate Device: NICE1
510(k) Number: K143197
Clearance Date: December 23, 2014
Submitter: Nice Recovery Systems, LLC

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

## 4. Description of Subject Device

This submission includes two models JKH-152 (private labelled as Cryon-X Pro) and JKH-151 (private labelled as Cryon-X One) as the subject devices. The private-label Cryon-X Pro has all the same features of combining cold, heat, contrast, and compression therapies as its original 510(k) cleared device in K223541, and Cryon-X One has the simplified features of cold and compression, which are the same as those of its original 510(k) cleared device in K223541. Each of the subject devices is an AC powered, software-controlled multimodality device, 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 is a prescriptive device, which 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 are indicated. It is optionally 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 and its accessories are clean and non-sterile. The device has a power switch, and then conducts the remaining operations on its touch screen, including the treatment temperature adjustment, air compression adjustment, and treatment time adjustment. The device works by circulating cooled or heated water and air through a treatment wrap that is placed on the treatment body area. The cooled or heated water circulates through the treatment wrap and provides cold or hot therapy, and the air compression inflates and deflates the treatment wrap to compress around the treatment body area. A connecting tube/hose is used to connect the device to the treatment wrap. The disposable or reusable wraps come with a variety of options to cover different body areas, including the universal, back, shoulder, ankle/foot, hip, knee, etc. To avoid any potential adverse skin reactions such as redness, irritation, and cod/hot injury, the sock/clothing should be worn by the patient prior to use.

**5. Indications for Use**

Cryon-X Pro

The private-label Cryon-X Pro device 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) is indicated.

The device may optionally provide DVT therapy, 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.

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

Cryon-X One

The private-label Cryon-X One device combines cold 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 be used by or on the order of licensed healthcare professionals in rehabilitation facilities/hospitals, 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 | Primary Predicate Device | Predicate Device | Predicate Device | Reference Device | Equivalence |
|---|---|---|---|---|---|---|
| 510(k) Number | K253150 | K223541 | K193550 | K143197 | K061866 | N/A |
| Submitter | JKH Health Co., Ltd. | JKH Health Co., Ltd. | Zenith Technical Innovations, LLC | Nice Recovery Systems, LLC | ThermoTek, Inc. | N/A |
| Device Name/Model | Cryon-X Cold Compression | Cold/Hot Compression | Therm-X | NICE1 | VascuTherm | N/A |
| Indications for Use | Cryon-X Pro<br>The private-label Cryon-X Pro device 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) is indicated.<br><br>The device may optionally provide DVT therapy, 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.<br><br>This device is intended to be used by or on the order of licensed healthcare professionals in rehabilitation facilities, outpatient clinics, athletic training settings, and home settings.<br><br>Cryon-X One<br>The private-label Cryon-X One device combines cold 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 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 post-surgical medical and/or surgical conditions for which localized thermal therapy (hot or cold) are indicated.<br><br>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.<br><br>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. | 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.<br><br>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.<br><br>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. | The Nice1 combines cold and compression therapies. It is intended to treat post-surgical and acute injuries to reduce edema, swelling,<br>and pain where cold and compression are indicated. It is intended to be used by or on the order of a healthcare professional in hospital,<br>outpatient clinics, athletic training settings, or home settings. | Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema.<br><br>Reduction of edema associated with soft tissue injuries such as bums, postoperative edema,<br>and ligament sprains.<br><br>Localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions.<br><br>Decrease the risk of deep venous thrombosis (DVT).<br><br>Aids the blood flow back to the heart.<br><br>Treat and assist healing of cutaneous ulceration (wounds), reduce would healing time,<br>enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning)<br>medications. | Substantially equivalent. See Note 1 below for details. |
| 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) | Health Care Professionals and lay users (under prescription) | Health Care Professionals and lay users (under prescription) | Identical |
| Prescription or OTC | Prescription | Prescription | 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 | 120 VAC, 50/60 Hz | 100-240 VAC, 50/60 Hz | Identical |
| Compliance with Voluntary Standards? | Yes | Yes | Yes | Yes | Yes | Identical |
| Electrical Safety<br>Mechanical Safety<br>Chemical Safety<br>Thermal Safety | Yes | Yes | Yes | Yes | Yes | Identical |

| | | | | | | |
|---|---|---|---|---|---|---|
| Radiation Safety? | | | | | | |
| Cold Therapy | Default: 50°F<br>Custom range: 41°F–55°F (unlockable to 34°F), optionally adjusted to the human body temperature of 99°F. | Default: 50°F<br>Custom: 41°F–55°F<br>Default, continuous: 50°F<br>Custom, continuous: 41°F – 50°F | Default: 34°F, 45°F, 55°F<br>Custom: 34°F – 55°F<br>Default, continuous: 40°F, 45°F, 50°F<br>Custom, continuous: 40°F – 50°F | 43°F–59°F | Default: 49°F<br>Custom: 43°F–49°F<br>Default, continuous: 49°F<br>Custom, continuous: 43°F – 49°F | Substantially equivalent. See Note 2 below for details. |
| Heat Therapy | Cryon-X Pro:<br>Default: 105°F<br>Custom range: 105°F–109°F, optionally adjusted to the human body temperature of 99°F.<br><br>Cryon-X One: N/A | Default: 105°F<br>Custom: 105°F–109°F<br>Default, continuous: 105°F<br>Custom, continuous: 105°F – 109°F | Default: 105°F, 107°F, 110°F<br>Custom: 105°F –110°F<br>Default, continuous: 105°F, 107°F<br>Custom, continuous: 105°F – 107°F | N/A | Default: 105°F<br>Custom: 100°F–105°F<br>Default, continuous: 105°F<br>Custom, continuous: 100°F – 105°F | Substantially Equivalent. See Note 3 below for details. |
| Edema Pressure Levels | Compression Therapy<br>Alternate mode：0 -75 mm Hg<br>Compression Therapy<br>Continuous mode：0 -75 mm Hg | Compression Therapy<br>Alternate mode：15 -75 mm Hg<br>Compression Therapy<br>Continuous mode：15 - 75 mm Hg | Available in four levels:<br>Lite (5 mm Hg)<br>Low (20 mm Hg)<br>Medium (45 mm Hg)<br>High (70 mm Hg)<br>For continuous treatment, available in three levels:<br>Low (20 mm Hg)<br>Medium (45 mm Hg)<br>High (70 mm Hg) | 0 -75 mm Hg | Compression Therapy<br>3 Settings:<br>Low (15 mm Hg)<br>Medium (30 mm Hg)<br>High (50 mm Hg) | Substantially equivalent. See Note 4 below for details. |
| Static or Intermittent Pressure | Both | Both | Both | Intermittent | Intermittent Pressure available | Identical |
| DVT Only | Optionally available | Available | Available for Therm-X Home Model | N/A | Available | Identical |
| DVT Pressure | Calf: 55 mmHg<br>Foot: 130 mmHg | Calf: 55 mmHg<br>Foot: 130 mmHg | Calf: 50 – 70 mmHg<br>Foot: 90 – 130 mmHg | N/A | Calf: 45 mmHg<br>Foot: 100 mmHg | Identical |
| Cycle Length (for Heat, Cold, And Compression) | Default: 30 minutes<br>Custom: 1 – 60 minutes | Default: 30 minutes<br>Custom: 1 – 60 minutes | Default: 10 or 20 minutes<br>Custom: 3 – 40 minutes<br>Continuous: 10 – 40 minutes active, 30-60 minutes rest | Default: 30 minutes | Default: 90 minutes | Identical |
| Contrast Therapy | Cryon-X Pro:<br>Heat: 105°F at default and 105°F–109°F adjustable, optionally adjusted to the human body temperature of 99°F.<br><br>Cold: 49°F at default and 41°F–55°F adjustable (unlockable to 34°F), optionally adjusted to the human body temperature of 99°F.<br><br>Cryon-X One: N/A | Heat: 105°F<br>Cold: 49°F | Heat: 105°F<br>Cold: 38°F | N/A | Heat: 105°F<br>Cold: 49°F | Substantially equivalent. See Note 5 below for details. |
| Cycle Length (for Contrast Therapy) | Heat: 10 minutes at default and 1 – 60 minutes adjustable<br>Cold: 20 minutes at default and 1 – 60 minutes adjustable | Heat: 10 minutes<br>Cold: 20 minutes | Heat: 3-10 minutes<br>Cold: 3-10 minutes<br>Total treatment: 6-60 minutes | N/A | Heat: 10 minutes<br>Cold: 20 minutes | Substantially equivalent. See Note 6 below for details. |
| 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. | N/A | 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 is combined with cold, heat, or contrast therapy | Available Edema Compression is combined with cold, heat, or contrast therapy | Available Edema Compression (Lite, Low, Medium, High) is combined with cold, heat, or contrast therapy | N/A | Available Edema Compression (Lite, Low, Medium, High) is combined with cold, heat, or contrast therapy | Identical |
| Edema Inflation and | Inflation: Up to 120 seconds | Inflation: Up to 120 | Inflation: Up to 120 seconds | Approximately 2 to | Inflation: Up to 120 | Identical |

| | | | | | | |
|---|---|---|---|---|---|---|
| Deflation | Deflation: Up to 30 seconds | seconds<br>Deflation: Up to 30 seconds | Deflation: Up to 30 seconds | 3 minutes of inflation and 1 minute of deflation | seconds<br>Deflation: Up to 30 seconds | |
| Store Cycle Usage Data | Available | Available | Available | N/A | Available | Identical |
| Reservoir Fluid Capacity | 420 mL | 350 mL | 650 mL | 300mL | 300mL | Different. See Note 7 below for details. |
| Recommended Coolant | Distilled Water | 90% Distilled Water, 10% Isopropyl Alcohol | 90% Distilled Water, 10% Isopropyl Alcohol | Water | 90% Distilled Water, 10% Isopropyl Alcohol | Substantially equivalent. See Note 8 below for details. |
| User Interface | Touch Screen | Touch Screen | Touch Screen | Touch Screen | Touch Screen | Identical |
| Dimensions | Cryon-X Pro: Approx. L282 x W220 x H230 mm<br><br>Cryon-X One: Approx. 210 x 200 x 210 mm | L295xW285xH295 mm | 15" L x 10.5" W x 9" H | 220 x 190 x 220 mm | L170xW170xH300 mm | Different. See Note 9 below for details. |
| Weight Approx. | Cryon-X Pro: Approx. 6.4kg<br><br>Cryon-X One: Approx. 4.5kg | 8.2kg | 15 lbs. when full of coolant | 4.5kg | 8.7kg | Different. See Note 10 below for details. |
| Types of Garments | Various anatomical thermal wraps/garments for different body areas, such as the Back, Elbow, Shoulder, Knee, Ankle, Hip.<br><br>DVT wraps/Garments: Calf and Foot | Various anatomical thermal garments for: Back, Elbow, Shoulder, Knee, Ankle, Hip.<br><br>DVT Garments: Calf and Foot | Various anatomical thermal garments for: Back, Elbow, Shoulder, Knee, Ankle, Hip.<br><br>DVT Garments: Calf and Foot | Various anatomical thermal garments | Various anatomical thermal garments for: Back, Elbow, Shoulder, Knee, Ankle, Hip.<br><br>DVT Garments: Calf and Foot | Identical |
| Patient Contacting Wrap | Thermal wrap/garment – nylon fabric on one side and velvet cloth on the other side<br><br>DVT wrap/garment – velvet on both sides | Thermal garment – nylon fabric on one side and velvet cloth on the other side<br><br>DVT garment – velvet on both sides | Thermal garment, reusable (multi-patient) – 30 denier nylon coated in urethane<br><br>Thermal garment, disposable (single-patient) – 200 denier nylon coated in urethane<br><br>DVT garment – 200 denier nylon coated in urethane | urethane coated nylon | Thermal garment– 200 denier nylon oxford<br><br>DVT garment – DuPont Softesse Medical Fabric (non-latex, non-woven) | Identical or substantially equivalent, and compatible with the predicate/reference device. To avoid any potential adverse skin reactions such as redness, irritation, and cod/hot injury, the sock/clothing should be worn by the patient prior to use. |
| Sterile/Non-Sterile | Non-sterile | Non-sterile | Non-sterile | Non-sterile | Non-sterile | Identical |
| Cleaning Disinfection Validation of Labeling | Yes | Yes | Yes | Yes | Yes | Identical |

**Substantially Equivalent Note 1:** With all the features of cold, heat, contrast, and compression therapies, Cryon-X Pro has the same Indications for Use as its original 510(k) cleared device in K223541. Although Cryon-X One only includes the cold and compression features and does not have the features of heat and contrast, it does not affect its intended use or fundamental technology. Similarly, the predicate device in K143197 only includes the cold and compression features and does not have the features of heat and contrast, and it has the substantially equivalent intended uses and technical characteristics to Cryon-X One. Therefore, Cryon-X One has the same Indications for Use as the predicate device in K143197, which is a subset of the Indications for Use in the original 510(k) cleared K223541.

**Substantially Equivalent Note 2:** The cold therapy of the subject device in this submission has the same default temperature of 50°F and the same temperature range of 41°F–55°F as its original 510(k) cleared device in K223541. In addition, if unlocked by the health care professionals or on the order of health care professionals, the subject device is able to reach 34°F, which is exactly the same as the predicate device in K193550. Therefore, it does not raise any new issues of safety or effectiveness.

Optionally, the subject device can be adjusted to the human body temperature of 99°F. It does not raise any new issues of safety, because the patient contacting wrap starts from the human body temperature of 99°F and decreases to the above mentioned cold therapy temperature.

**Substantially Equivalent Note 3:** The heat therapy of the subject device in this submission has the same default temperature of 105°F and the same temperature range of 105°F–109°F as its original 510(k) cleared device in K223541. Therefore, it does not raise any new issues of safety or effectiveness.

Optionally, the subject device can be adjusted to the human body temperature of 99°F. It does not raise any new issues of safety, because the patient contacting wrap starts from the human body temperature of 99°F and increases to the above mentioned heat therapy temperature. Such a similar case can be found in the reference K061866.

**Substantially Equivalent Note 4:** Although the edema pressure level of original 510(k) cleared device in K223541 is written as 15-75 mmHg, it actually starts from 0. Therefore, in this submission, we correct the edema pressure level to be 0-75 mmHg, and such an exactly same range can be found in the predicate K143197. Therefore, it does not raise any new issues of safety or effectiveness.

**Substantially Equivalent Note 5:** The default contrast therapy of the subject device is exactly the same as that of its original 510(k) cleared device in K223541, and the adjustable temperature range of the subject device is exactly the same as that of its original 510(k) cleared device in K223541 for the heat therapy and the cold therapy, respectively. For more discussion, please see the above Note 2 and Note 3. Therefore, it does not raise any new issues of safety or effectiveness.

**Substantially Equivalent Note 6:** The default cycle length of the contrast therapy for the subject device is exactly the same as that its original 510(k) cleared device in K223541, and the adjustable cycle range of the subject device is exactly the same as that of its original 510(k) cleared device in K223541 for the heat therapy and the cold therapy, respectively. Therefore, it does not raise any new issues of safety or effectiveness.

**Substantially Equivalent Note 7:** The reservoir fluid capacity of the subject device is larger than that of its original 510(k) cleared device in K223541, while it is smaller than that of the predicate device in K193550. Such a case can be also found in our earlier cleared K223541. Therefore, the different reservoir fluid capacity between the subject device and the predicate device does not raise any new issues of safety or effectiveness.

**Substantially Equivalent Note 8:** The subject device can use the same coolant of 90% Distilled Water and 10% Isopropyl Alcohol as its original 510(k) cleared device in K223541. To make the subject device more user friendly, we tested and verified that the Isopropyl Alcohol can be removed, and it is fine to only use water, similar to the predicate device in K143197. Therefore, it does not raise any new issues of safety or effectiveness.

**Substantially Equivalent Note 9:** The difference of dimensions does not change the product performance or parameters, which will not raise any new issue of the safety or effectiveness. Such a case can be also found in our earlier cleared K223541.

**Substantially Equivalent Note 10:** The difference of weight does not change the product performance or parameters, which will not raise any new issue of the safety or effectiveness. Such a case can be also found in our earlier cleared K223541.

**7. Substantial Equivalence**

As discussed above and shown in the above table, the subject device in this submission has the identical or substantially 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. 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 coolant alarm. The microprocessor and pump units can be powered by the 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 or equivalent 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.).

**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) 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".

In addition to the compliance of voluntary standards, 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.

**9. Clinical Testing**

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

**10. 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.