March 8, 2023

Suzhou MicroPort RehabTech (Group) Co., Ltd.
℅ Yunfang Sun
Senior Specialist, Regulatory Affairs
MicroPort Sinica Co., Ltd.
No. 1601 ZhangDong Rd, ZJ Hi-Tech Park
Shanghai, 201203
China

Re: K222136
Trade/Device Name: Cryo-Thermo Compression Device
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP, ILO
Dated: January 13, 2023
Received: January 13, 2023

Dear Yunfang Sun:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222136

Device Name
Cryo-Thermo Compression Device

Indications for Use *(Describe)*
Cryo-Thermo Compression Device combines cold, heat and compression therapies.

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 be used by, or on the order of, licensed healthcare professionals in rehabilitation facilities, outpatient clinics and athletic training settings.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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

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

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

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

510(k) Summary

510(k) Submitter:	Suzhou MicroPort RehabTech (Group) Co., Ltd. Part of building3#, 112 Fangzhong Street, Suzhou Industrial Park,201203 Suzhou, PEOPLE'S REPUBLIC OF CHINA
Contact Person:	Liang Hong hongliang@microport.com Phone: +86-0512-65001777-2257
Date Prepared:	January 11, 2023
Device Name:	Cryo-Thermo Compression Device
Device Classification Name:	Powered Inflatable Tube Massager
Regulation Number:	21 CFR 890.5650
Classification Panel:	Physical Medicine
Classification Product Code:	IRP, ILO
Device Class:	Class II

1. Substantial Equivalence Claimed To

Cryo-Thermo Compression Device is substantially equivalent to Therm-X cleared under (K193550) and Med4 Elite™ cleared under K171685. The predicate devices are listed in Table 1.

Table 1 Table of Predicates

Comparison Device	Primary Predicate Device	Secondary Predicate Device
Trade Name:	Therm-X	Med4 Elite™
Common Name:	Massager, Powered Inflatable Tube	Heat and/or Cold and Compression Therapy
510(k) Number:	K193550	K171685
510(k) Submitter /Holder:	Zenith Technical Innovations, LLC.	Cool Systems, Inc.
Classification:	Class II	Class II
Regulation Number:	21 CFR 890.5650	21 CFR 890.5650

Classification Panel:	Physical Medicine	Physical Medicine
Product Code:	IRP, ILO, JOW	IRP, ILO

2. Indication for Use

Cryo-Thermo Compression Device combines cold, heat and compression therapies.

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 be used by, or on the order of, licensed healthcare professionals in rehabilitation facilities, outpatient clinics and athletic training settings.

3. Intended Use Population

Cryo-Thermo Compression Device is intended for adults only (greater than 21 years of age).

4. Device Description

Cryo-Thermo Compression Device, Model Number: FGK002, is an AC powered, software-controlled device, designed to be used in rehabilitation facilities, outpatient clinics and athletic training settings and under the direction, prescription, or supervision of a licensed healthcare professional.

Cryo-Thermo Compression Device features iceless cold therapy, heat therapy and intermittent pneumatic compression therapy.

Cryo-Thermo Compression Device provides various inflatable wraps for thermal treatment (heat or cold) of the elbow, shoulder, ankle, hand-wrist or knee. The wraps are reusable for a single patient and can be cleaned if necessary.

Cryo-Thermo Compression Device is controlled by a touch screen interface, allowing the user to manage in the therapy modalities as well as easily adjust treatment temperature, compression level and time settings.

Cryo-Thermo Compression Device consists of a main equipment, wraps and accessories. The main equipment includes a control unit, a hose and a power cable. The drainpipe and the ice stick are accessories which can be ordered upon request. It is approximately 17.64lbs (8kg) when reservoir is full of coolant. And, it is recommended to use 10% ethanol with 90% distilled water as the coolant.

5. Substantial Equivalence

The subject device, Cryo-Thermo Compression Device, is substantially equivalent to the primary predicate Therm-X (K193550) by Zenith Technical Innovations, LLC. (Zenith) and the secondary predicate Med4 Elite™ (K171685) by Cool Systems, Inc. currently on the market.

The table below provides a detailed comparison of the Cryo-Thermo Compression Device to predicate devices.

Table 2 Detailed Comparison of the Subject and Predicate Device

Characteristics	**Cryo-Thermo Compression Device (Subject Device)**	**Therm-X （K193550） (Primary Predicate)**	**Med4 Elite™ (Secondary Predicate)**	**Comparison**
Indications for Use	Cryo-Thermo Compression Device combines cold, heat and compression therapies. 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 be used by, or on the order of, licensed healthcare professionals in rehabilitation facilities, outpatient clinics and	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 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 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 or contrast) are indicated. It is intended to be used by, or on the order of,	All three devices combine cold, heat and compression therapies, the Cryo-Thermo Compression Device does not provide contrast therapy compared to predicate devices Therm-X and Med4 Elite™. Cryo-Thermo Compression Device has the same intended use as the predicate devices Therm-X and Med4 Elite™. The Cryo-Thermo Compression Device is not indicated for decreasing risk of DVT and not used in home setting, which is covered by additional

Characteristics	Cryo-Thermo Compression Device (Subject Device)	Therm-X （K193550） (Primary Predicate)	Med4 Elite™ (Secondary Predicate)	Comparison
	athletic training settings.	the risk of the formation of deep venous thrombosis (DVT) by aiding blood flow back to the heart via lower extremity limb compression. 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.	licensed healthcare professionals in rehabilitation facilities, outpatient clinics, and athletic training settings.	indications and functionality of the Therm-X Home.
Intended User	Health Care Professionals only (Prescription use)	Health Care Professionals and lay users (under prescription)	Health Care Professionals only (Prescription use)	All three devices are prescription use only. Cryo-Thermo Compression Device and secondary predicate are only used by health care professionals.

Characteristics	**Cryo-Thermo Compression Device (Subject Device)**	**Therm-X （K193550） (Primary Predicate)**	**Med4 Elite™ (Secondary Predicate)**	**Comparison**
Number of Patients that can be treated at one time	One	One	Two	Both subject device Cryo-Thermo Compression Device and primary predicate Therm-X are designed to treat one patient at a time**.**
Functions				
Heat Therapy	38℃ (100.4℉) or 40℃ (104℉)	Default: 40.5℃（105℉）, 41.6℃（107℉）, 43℃（110℉）; Custom: 40.5℃ - 43℃（105℉ -110℉）; Default, continuous: 40.5℃ (105℉), 41.6℃（107℉）; Custom, continuous: 40.5℃-41.6℃（105℉ -107℉）;	35℃ - 45℃ (95℉ -113℉)	The maximum temperature set point for heat therapy of Cryo-Thermo Compression Device is lower compared with the primary predicate Therm-X. Furthermore, the both temperature set points (38℃ or 40℃) of Cryo-Thermo's heat therapy are within the temperature range of the secondary predicate Med4 Elite™. There is no new safety and effectiveness issue.

Characteristics	**Cryo-Thermo Compression Device (Subject Device)**	**Therm-X （K193550） (Primary Predicate)**	**Med4 Elite™ (Secondary Predicate)**	**Comparison**
Cold Therapy	6℃ -15℃ (42.8°F-59°F),	Default: 1.1℃ (34°F), 7.2℃ (45°F), 12.7℃ (55°F); Custom: 1.1℃ -12.7℃ (34°F-55°F); Default, continuous: 4.4℃ (40°F), 7.2℃ (45°F), 10℃ (50°F); Custom, continuous: 4.4℃ - 10℃ (40°F - 50°F);	3.33℃ -15.56℃ (38°F -60°F)	The minimum and maximum temperature set points for cold therapy of Cryo-Thermo Compression Device are higher compared with the primary predicate Therm-X. Furthermore, the temperature range for cold therapy of Cryo-Thermo can be covered by the secondary predicate Med4 Elite™. There is no new safety and effectiveness issue.
Compression range	Available in five levels: Off (0mmHg), Low (15mmHg), Medium-Low (30mmHg), Medium-High (50mmHg), High (70mmHg)	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 four levels： Low (5 - 15 mm Hg), Medium-Low (5 - 30 mm Hg), Medium (5 - 50 mmHg), High (5 - 75 mmHg)	The Cryo-Thermo Compression Device has a same maximum compression level as the primary predicate Therm-X, and the pressure value available in each level can

Characteristics	Cryo-Thermo Compression Device (Subject Device)	Therm-X （K193550） (Primary Predicate)	Med4 Elite™ (Secondary Predicate)	Comparison
		available in three levels: Low (20 mm Hg) Medium (45 mm Hg) High (70 mm Hg)		be covered by the secondary predicate Med4 Elite™.
Static or Intermittent Pressure	Intermittent Pressure available	Static and Intermittent Pressure	Intermittent Pressure available	All the three devices can provide intermittent pressure.
Treatment Time Setting (for Heat, Cold and Compression)	Single Treatment time: 10 min - 40min **Continuous use:** Cycle Length: Treatment time: 10 min - 40min; Rest time: 30 - 60min. Cycle number: 1-6 cycles	Default: 10 or 20 minutes Custom: 3 - 40 minutes **Continuous use:** Cycle Length: 10 - 40 minutes active, 30 - 60 minutes rest Continuous Treatment Cycle: Available on Therm-X Home.	Heat: 5 to 30 minutes, 15 minutes default; Cold: 5 to 60 minutes, 15 minutes default; Compression Only: 5 to 60 minutes, 15 minutes default **"Snooze" Function:** Available	Regard to single treatment: The single treatment time of Cryo-Thermo Compression Device can be covered by primary predicate Therm-X, which is also within the treatment time range for cold or/and compression therapy of the secondary predicate Med4 Elite™. For continuous use: The continuous use of Cryo-Thermo Compression Device can be covered by

Characteristics	**Cryo-Thermo Compression Device (Subject Device)**	**Therm-X （K193550） (Primary Predicate)**	**Med4 Elite™ (Secondary Predicate)**	**Comparison**
				primary predicate Therm-X, Cryo-Thermo Compression Device provides same cycle length, smaller cycle number and shorter total treatment time, compared with the primary predicate Therm-X (based on information from the published IFU of Therm-X Home). Compared with the secondary predicate Med4 Elite™ in cold therapy, Cryo-Thermo Compression Device provides shorter cycle length, same cycle number and shorter total treatment time (based on information from the published IFU of Med4 Elite™).

Characteristics	Cryo-Thermo Compression Device (Subject Device)	Therm-X （K193550） (Primary Predicate)	Med4 Elite™ (Secondary Predicate)	Comparison
				The safety and effectiveness of Cryo-Thermo's continuous use have been demonstrated by the skin temperature testing. Thus, there is no new safety and effectiveness issue.
Physical Unit				
Dimensions	13.7"L×5.75"W×11.02"H (34.8×14.6×28.0cm)	15"L×10.5"W×9"H (38.1×26.67×22.86cm)	32.5"L×24.75"W×43"H (83×63×109cm)	The dimension of Cryo-Thermo Compression Device is similar to the primary predicate Therm-X. The cold therapy of the secondary predicate Med4 Elite™ is conducted by vapor compression with a

Characteristics	Cryo-Thermo Compression Device (Subject Device)	Therm-X （K193550） (Primary Predicate)	Med4 Elite™ (Secondary Predicate)	Comparison
				larger reservoir, thus Med4 Elite™'s dimension is larger than the Cryo-Thermo Compression Device.
Weight	17.64 lbs (8kg) when full of coolant	15 lbs. when full of coolant	172 lbs (78 kg)	Cryo-Thermo Compression Device is similar in weight with the primary predicate Therm-X. The cold therapy of the secondary predicate Med4 Elite™ is conducted by vapor compression with a larger reservoir, thus Med4 Elite™ is heavier than the Cryo-Thermo Compression Device.
Chilling Mechanism	Thermoelectric	Thermoelectric	Vapor compression	The Cryo-Thermo Compression Device has the same chilling mechanism with the

Characteristics	Cryo-Thermo Compression Device (Subject Device)	Therm-X （K193550） (Primary Predicate)	Med4 Elite™ (Secondary Predicate)	Comparison
				primary predicate Therm-X.
Heating Mechanism	Thermoelectric	Thermoelectric	Resistance heaters	The Cryo-Thermo Compression Device has the same heating mechanism with the primary predicate Therm-X.
Reservoir Fluid Capacity	600mL	650 mL	Heat reservoir: 1 gallon (3.8 L) Cold reservoir: 1 gallon (3.8 L)	The reservoir fluid capacity of the Cryo-Thermo Compression Device is similar to the primary predicate Therm-X. The secondary predicate Med4 Elite™ has a larger reservoir fluid capacity since it is designed for maximum two patients at a treatment time, while Cryo-Thermo Compression Device and the primary predicate Therm-X are for

Characteristics	Cryo-Thermo Compression Device (Subject Device)	Therm-X （K193550） (Primary Predicate)	Med4 Elite™ (Secondary Predicate)	Comparison
				one patient at a treatment time.
User Interface	Touch Screen	Touch Screen	Touch Screen	Same
Recommended Coolant	90% Distilled Water, 10% Ethanol	90% Distilled Water, 10% Isopropyl Alcohol	Distilled Water	Cryo-Thermo Compression Device recommends the similar coolant to the Therm-X. Each device is able to attain desired performance requirements with its recommended coolant.
Electrical				
Line Voltage	100-240 VAC	100-240 VAC	100-240 VAC	Same
Line Frequency	60 Hz	50/60 Hz	50-60 Hz	Same
Electrical Safety Standards	IEC 60601-1: 2005 + AMD 1:2012+AMD2:2020 Type B IEC 60601-1-2	ANSI/AAMI ES60601-1:2005/(R)2012 CAN/CSA C22.2 No.60601-1:2014 Type B IEC 60601-1-2	ANSI/AAMI ES60601-1:2005/(R)2012 CAN/CSA C22.2 No. 60601-1:2014 Type B	The subject device was tested per IEC 60601-1:2005 + AMD 1:2012+AMD2:2020, moreover, tests to cover the US national differences were supplemented as an attachment to the IEC

Characteristics	Cryo-Thermo Compression Device (Subject Device)	Therm-X （K193550） (Primary Predicate)	Med4 Elite™ (Secondary Predicate)	Comparison
				60601-1 report, which was shown to comply with the required components of ANSI/AAMI ES60601-1:2005/(R)2012 in support of substantial equivalence.
Environment				
Operating Temperature	41°F – 104°F (5°C – 40°C)	60°F – 80°F (16°C – 27°C)	50°F –90°F (10°C – 32°C)	Cryo-Thermo Compression Device works in a wider temperature environment than Therm-X and Med4 Elite™.
Storage Temperature	32°F – 122°F (0°C – 50°C)	33°F – 122°F (1°C – 50°C)	33°F – 122°F (1°C to 50°C)	Cryo-Thermo Compression Device has similar Storage Temperature to Therm-X and Med4 Elite™.
Operating Humidity	25 to 80% Non-condensing	Below 60% Non-condensing	30 to 90% Non-condensing	Cryo-Thermo Compression Device is defined in a RH range environment wider than the first predicate Therm-X, but Cryo-Thermo Compression Device works within the

Characteristics	**Cryo-Thermo Compression Device (Subject Device)**	**Therm-X （K193550） (Primary Predicate)**	**Med4 Elite™ (Secondary Predicate)**	**Comparison**
				RH range environment of secondary predicate Med4 Elite™.
Storage Humidity	0 to 95%, Non-condensing	Below 60% Non-condensing	10 to 95% Non-condensing	Cryo-Thermo Compression Device stores in a wider storage humidity range than Therm-X, but has a same maximum storage humidity with Med4 Elite™.
Operating Atmospheric Pressure	860hPa – 1060hPa	700 hPa – 1060 hPa	700 hPa – 1060 hPa	Cryo-Thermo Compression Device works at similar atmospheric pressure as the Therm-X and the Med4 Elite™.

Characteristics	**Cryo-Thermo Compression Device (Subject Device)**	**Therm-X （K193550） (Primary Predicate)**	**Med4 Elite™ (Secondary Predicate)**	**Comparison**
		Wraps		
Types of Wraps	Various anatomical wraps for: Elbow, Knee, Hand-Wrist, Ankle, Shoulder	Various anatomical thermal garments for: Back, Elbow, Shoulder, Knee, Ankle, Hip. DVT Garments: Calf and Foot	Various anatomical wraps in different sizes for: Straight Knee, Articulated Knee, Elbow, Ankle, Shoulder, Back, Hip-Groin, Hand-Wrist, Flexed Elbow, Half-leg boot	Cryo-Thermo has same anatomical wrap in Elbow, Knee, Ankle and Shoulder compared to the primary predicate Therm-X. Furthermore, all the five types of wraps of Cryo-Thermo can be covered by the secondary predicate Med4 Elite™. No new issues of safety and effectiveness.
Patient Contacting Material	Wrap Envelope : nylon6 Wrap and Fixing Band Edge : T/C cloth, Fixing Band Envelope : 427 polyester brushed fabric, Connector : ABS plastic	Thermal garment, reusable (multi patient) – 30 denier nylon coated in urethane; Thermal garment, disposable (single patient) – 200 denier nylon coated in urethane;	70 Denier nylon, Silcryn (hose covering)	All patient contacting materials of Cryo-Thermo Compression Device wrap were evaluated according to ISO 10993, and no new safety concerns were found.

Characteristics	**Cryo-Thermo Compression Device (Subject Device)**	**Therm-X （K193550） (Primary Predicate)**	**Med4 Elite™ (Secondary Predicate)**	**Comparison**
		DVT – 200 denier nylon coated in urethane		
Biocompatibility	Cytotoxicity testing per ISO 10993-5 Sensitization testing per ISO 10993-10 Irritation testing per ISO 10993-10	Cytotoxicity testing per ISO 10993-5 Sensitization testing per ISO 10993-10 Irritation testing per ISO 10993-10	Cytotoxicity testing per ISO 10993-5 Sensitization testing per ISO 10993-10 Irritation testing per ISO 10993-10	Same
Sterile /Non-Sterile	Non-sterile only	Non-sterile only	Non-sterile only	Same
Reusable Wraps	Yes, Single-Patient use reusable wraps	Yes, Multi-Patient use reusable wraps	Yes, Multi-Patient use reusable wraps	The reusable wraps of Cryo-Thermo are only used for single patient and can be cleaned if necessary, according to the cleaning instructions in IFU.
Expected Life of reusable wraps	One year, based on frequency of use and continued functional performance.	Based on frequency of use and continued functional performance.	Based on frequency of use and continued functional performance.	The expected life of Cryo-Thermo's single-patient reused wraps has been verified.

Characteristics	**Cryo-Thermo Compression Device (Subject Device)**	**Therm-X （K193550） (Primary Predicate)**	**Med4 Elite™ (Secondary Predicate)**	**Comparison**
Validation of cleaning or/and disinfection for reusable wraps	Yes.	Yes - for Multi-Patient use reusable wraps.	Yes	The effectiveness of the cleaning method of Cryo-Thermo's single-patient reused wraps has been validated.

The rationale for the substantial equivalence of the subject device and the predicate devices is based on the same technical principles of providing cold or heat therapy combined with intermittent pneumatic compression as well as on comparable performances for the same intended use. Although, there are differences in the setting range of treatment parameters between the Cryo-Thermo and the predicate devices, the maximum limits of all Cryo-Thermo treatment parameters are equal to or less than the maximum values of corresponding treatment parameters of both predicate devices.

The subject device and predicate devices have the same intended use and similar technological characteristics with the exception that the patient contacting materials of the subject device differ from the predicate devices. All the patient contacting materials of Cryo-Thermo Compression Device wrap were evaluated according to ISO 10993, and no new safety and effectiveness concerns were found.

In summary, any differences between the subject device and the predicate devices do not raise new issues of safety and effectiveness. The subject device Cryo-Thermo Compression Device is as safe, as effective, and performs comparably to predicate devices Therm-X and Med4 Elite™ for the same intended use.

6. Summary of Performance Data

Cryo-Thermo Compression Device and the software were verified and validated in accordance with documented testing plans to ensure conformance with established performance criteria. See below for the tests performed.

- **Biocompatibility Evaluation**

The biocompatibility evaluation for Cryo-Thermo Compression Device is conducted based on the FDA guidance document "*Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'*". The patient contacting components are categorized as surface medical device with prolonged intact skin contact. Then, information of the safe history of the materials and their manufacturing processes are collected and assessed. In addition, relevant biocompatibility endpoints are identified, and representative components are analyzed and selected to conduct biocompatibility testing. The wrap patient contact materials of Cryo-Thermo Compression Device were verified in accordance with the following standards:

• ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

• ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

• ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for Irritation and Skin Sensitization.

In conclusion, the overall biological safety conclusion can be drawn that the biocompatibility risk of Cryo-Thermo Compression Device is acceptable.

- **Electrical Safety and Electromagnetic Compatibility (EMC)**

Electrical safety and electromagnetic compatibility testing were performed in accordance with following standards:

a) IEC 60601-1:2005+ AMD1:2012+AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
In addition, the US National Differences are tested as a supplement to the IEC 60601-1 testing.

b) IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

Testing results indicated that the device is safe.

- **Software Verification and Validation Testing**

Software tests were conducted to satisfy the requirements of the FDA guidance on Content of Premarket Submissions for Software Contained in Medical Devices and IEC 62304 Medical Device Software- Software Life Cycle Processes. The software contained in Cryo-Thermo Compression Device was considered a "Moderate" level of concern. The testing demonstrated that Cryo-Thermo Compression Device does not raise any new issues of safety and effectiveness as compared to the predicate devices.

- **Bench Performance Testing**

The device performances were tested to verify the device's functional properties. The following performance tests were completed.

1	Temperature accuracy	To verify the tolerance between the wrap temperature and the target value set on the device.
2	The time required to reach the target temperature	To verify the time spent to achieve the target temperature set on the device.
3	Pressure accuracy	To verify the tolerance between the wrap pressure and the target value set on the device.
4	Timing accuracy	To verify the tolerance between the duration of treatment/rest and the target value set on the device.
5	Water flow rate	To verify the flow rate of water circulation under the working condition.
6	Water pressure	To verify the pressure of water circulation under the working condition.
7	Wrap seam strength	To verify the wrap does not burst or deform when the pressure exceeds the maximum pressure.
8	Hose function	To verify the hose does not leak while under maximum pressure for the maximum duration of use.
9	Failure mode test	To verify the device can release the pressure if there is a software failure.

Testing results indicated that Cryo-Thermo Compression Device conforms to its predetermined specifications and operates within safety limits.

- **Skin Temperature Testing**

As required by the FDA guidance document "***Guidance Document for the Preparation of Premarket Notification (510(k) Applications for Heating and Cooling Devices***", the Cryo-Thermo Compression Device was tested for skin temperatures in the worst-case use scenario on healthy volunteers who provided informed consents. The skin temperature change within 5 minutes' time window and the temperature range at the skin surface where the device is applied were measured in the skin temperature testing. The minimum skin temperature measured can achieve as low as 7.0℃ (44.6℉) and the maximum temperature can arrive as high as 44.2℃ (111.6℉), and these skin temperatures are included on the Instruction for Use.

Based on these results, it was concluded that Cryo-Thermo Compression Device didn't cause any thermal damage or cold injury to the skin. The studies demonstrated that there are no safety and effectiveness issues created by the device and that Cryo-Thermo Compression Device is as safe and effective as the predicate devices.

- **Cleaning & Expected life Testing**

Cryo-Thermo Compression Device wraps are intended for single-patient use and can be cleaned if necessary. Instructions for how to clean the wrap are provided in the IFU. Such cleaning instructions have been validated as per FDA guidance document "***Guidance for Industry and Food and Drug Administration Staff: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling***" issued on March 17, 2015.

Expected life is estimated based on the frequency of use and is verified by continued functional performance throughout service life. The main equipment is expected for a use life of 5 years, and the accelerated life test has been performed to confirm the safe use for the duration of the expected life. The use life of the wraps is expected for 1 year, and fatigue test is adopted to verify the expected life of the wraps, and the test accounts for the effect of repeated cleaning of the wraps.

7. Conclusion

The non-clinical testing data demonstrate the technological characteristics of the subject device are equivalent to the predicate devices and provide evidence that the Cryo-Thermo Compression Device performs as intended in the specified use conditions. Any differences between the subject device and the predicate devices do not raise new questions of safety and effectiveness, hence the subject device Cryo-Thermo Compression Device is as safe, as effective, and performs comparably to the predicate devices for the same intended use.