April 3, 2026

Chengdu Cryo-Push Medical Technology Co.,Ltd
℅ Lucy Yan
Official Correspondent
Shenzhen Joyantech Consulting Co. , Ltd.
1713a, 17th Floor, Block A, Zhongguan Times Square
Liuxian Ave., Xili Town, Nanshan District
Shenzhen, GuangDong 518100
China

Re: K252386
Trade/Device Name: Hot and Cold Compression System (A02-C-032)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Codes: IRP, ILO
Dated: November 12, 2025
Received: November 12, 2025

Dear Lucy Yan:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Digitally signed by
ZACHARY MCKINNEY -S
Date: 2026.04.03
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for 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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252386

Device Name
Hot and Cold Compression System (A02-C-032)

Indications for Use *(Describe)*
The device combines cold, heat and compression therapies. It is indicated to treat post-surgical and acute injuries to reduce edema, swelling and pain for which cold and compression are indicated; and it is 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.

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510(k) Summary
K252386

This summary of 510(k) information is submitted as required by requirements of SMDA and 21 CFR §807.92.

1 Administrative Information

Submission Date	July. 15, 2025
Manufacturer information	Submitter's Name: Chengdu Cryo-Push Medical Technology Co., Ltd. Address: 102, 105, Zone 20, Huayin Industrial Port, No.618, Kexing Road(West), Wenjiang District, Chengdu 611137 Sichuan P.R. China Contact person: Zhang Peiyong TEL: +86 18086852687
Submission Correspondent	Company: Shenzhen Joyantech Consulting Co., Ltd Address: 1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong Province, China Contact person: Ms Lucy Yan E-Mail: lucy@cefda.com; Tel: +86-755-86069197
Establishment registration number	3011491271

2 Device Information

Type of 510(k)	Traditional
Common name of the device	Massager, Powered Inflatable Tube
Trade name of the device	Hot and Cold Compression System
Type/Model of the device	A02-C-032
Classification information	Classification panel: Physical Medicine Classification name: Powered Inflatable tube massager Regulation Number: 21 CFR 890.5650 Device Class: II Product Code: IRP, ILO

3 Primary predicate Device Information and Reference predicate Device Information

Primary Predicate Device: Med4 Elite

Sponsor:	Cool Systems, Inc.
Device:	Med4 Elite Model(s): 650550
510(K) Number:	K171685
Product code:	IRP, ILO
Approval date:	August 29, 2017

Reference Device: Therm-X

Sponsor:	Zenith Technical Innovations, LLC.
Device:	Therm-X Model(s): Therm-X Home and Ther m-X AT
510(K) Number:	K193550
Product code:	IRP, ILO, JOW
Approval date:	December 20, 2019

4 Device Descriptions

Cryopush Hot and Cold Compression System (model: A02-C-032) is an AC powered, software-controlled multimodality device, designed to be used in a clinical setting, and under the direction and supervision of a licensed healthcare professional in rehabilitation facilities, outpatient clinics and athletic training settings. The device features iceless cold therapy, heat therapy, and intermittent pneumatic compression therapy for single patients at a time. The device is designed to be compatible with the pre-existing portfolio of ergonomic Cryopush cuffs made for specific body parts (e.g., shoulder, elbow, knee, ankle, back, etc.). The cuffs are flexible water circulating cuffs that apply to the body to deliver cold, heat, and/or compression therapy. The cuff is comprised of an inner airbag and water bag and an Outer Sleeve.

The A02-C-032 is controlled by an intuitive touch button and LED display, allowing the user to manage the therapy modalities as well as easily adjust and monitor treatment times, temperature and compression settings.

The physical description of the A02-C-032 is a compact unit with four caster wheels. It has one reservoir – holding cold water or hot water. The water reservoirs, pumps, cold engine, valves, power supplies and any other electronics are inside a covered enclosure made out of both plastic and sheet metal that can only be accessed with a tool.

The device mainly composed of a main unit, a power cord, various of cuffs and a connection hose. The cuffs are provided for single-patient use. It is approximately 16.5kg when reservoir is empty. it is recommended to use only distilled water as the coolant.

5 Intended Use/ Indications for Use

The device combines cold, heat and compression therapies. It is indicated to treat post-surgical and acute injuries to reduce edema, swelling and pain for which cold and compression are indicated; and it is 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.

6 SE Comparisons

The subject device Hot and Cold Compression System (model: A02-C-032) has the same intended use and indications for use as the predicate devices and uses equivalent overall design and operating principals as the predicate devices. Any minor differences between the subject device and the listed predicate device do no raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate device for its intended use. Therefore, the subject device may be found substantially equivalent to its predicate device. The subject device is compared with the following Predicate Devices in terms of intended use, design, specifications, and performance:

Items	New Device	Primary Predicate Device (K171685) Med4 Elite™	Secondary Predicate Device (K193550) Therm-X	Comparison
Product code	IRP, ILO	IRP, ILO	IRP, ILO, JOW	/
Regulation number	21 CFR 890.5650	21 CFR 890.5650	21 CFR 890.5650	/
Device class	Class II	Class II	Class II	/
Manufacturer	Chengdu Cryo-Push Medical Technology Co., Ltd.	Cool Systems®, Inc.	Zenith Technical Innovations, LLC.	/
Intended use	The device combines cold, heat and compression therapies. It is indicated to treat post-surgical and acute injuries to reduce edema, swelling and pain for which cold and compression are indicated; and it is 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.	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 postsurgical medical and/or surgical conditions for which localized thermal therapy (hot or cold or contrast) are indicated. It is intended to be used by or on the order of licensed healthcare professionals in rehabilitation facilities, outpatient clinics and athletic training 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 postsurgical medical and/or surgical conditions for which localized thermal therapy (hot or cold) are indicated. Therm-X Home systems also provide DVT therapy. ThermX 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. Therm-X (Therm-X Home and Therm-X AT) is intended to be used	Same

Items	New Device	Primary Predicate Device (K171685) Med4 Elite™	Secondary Predicate Device (K193550) Therm-X	Comparison
			by, or on the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, athletic training settings, and home settings.	
Intended Users	Health Care Professionals only (Prescription use)	Health Care Professionals only (Prescription use)	Health Care Professionals and lay users (under prescription)	Same
Intended Use Environment	Intended for indoor use only such as rehabilitation clinics, outpatient clinics, athletic training settings	Intended for indoor use only such as rehabilitation clinics, outpatient clinics, athletic training settings	in rehabilitation facilities, outpatient clinics, athletic training settings, and home settings.	Same
Number of Patients that can be treated at one time	One	Two	One	SE
Heat Therapy	Available without and with compression Adjustable range 38~45℃, 1℃ increment. Adjustable range 0~75 mmHg, 15mmHG increment.	Available without and with compression (Low)	Default: 105°F, 107°F, 110°F Custom: 105°F -110°F Default, continuous: 105°F, 107°F Custom, continuous: 105°F - 107°F	SE
Heat Therapy Treatment Time	Adjustable range 10-40 min, 5 min increment. Default setting: 20 minutes	5 to 30 minutes Default setting: 15 minutes	Default: 10 or 20 minutes Custom: 3 - 40 minutes Continuous: 10 - 40 minutes active, 30-60 minutes rest	Different Note 1
Cold Therapy	Available without and with Compression Adjustable range 4~16℃, 1℃ increment. Adjustable range 0~75 mmHg, 15mmHG increment.	Available without and with compression (Low, Medium-low, Medium, High)	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	SE

Items	New Device	Primary Predicate Device (K171685) Med4 Elite™	Secondary Predicate Device (K193550) Therm-X	Comparison
Cold Therapy Treatment Time	Adjustable range 20~60 min, 5 min increment. Default setting: 40 minutes	5 to 60 minutes Default setting: 15 minutes	Default: 10 or 20 minutes Custom: 3 – 40 minutes Continuous: 10 – 40 minutes active, 30-60 minutes rest	Different Note 1
Contrast Therapy	N/A	Available Heat: 1 – 10 minutes, default 3 minutes Cold: 1 – 10 minutes, default 3 minutes Total treatment 15 – 90 minutes, default 30 minutes	Available for ThermX AT Model only Heat: 105°F Cold: 38°F Cycle Length (for Contrast Therapy) Heat: 3-10 minutes Cold: 3-10 minutes Total treatment: 6-60 minutes	Different Note 2
Compression Only	Adjustable range 15~75 mmHg; 15mmHg increment.	Available in four levels Low (5 – 15 mm Hg) Medium-Low (5 – 30 mm Hg) Medium (5 -50 mm Hg) High (5 -75 mm Hg)	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)	SE
Static or Intermittent Pressure	Intermittent Pressure available	Intermittent Pressure available	Both	Same
Compression Only Treatment time	Adjustable range 10~60 min, 5 min increment. 10 minutes default	5 to 60 minutes 15 minutes default	Default: 10 or 20 minutes Custom: 3 – 40 minutes Continuous: 10 – 40 minutes active, 30-60 minutes rest	Different Note 1
Heat Reservoir Temperature Range	38~45℃	95 -113°F (35 - 45°C)	105°F – 110°F	Different Note 3
Cold Reservoir Temperature Range	4~16℃	38 - 60°F (3.33 -15.56°C)	34°F – 55°F	
“Snooze” Function	N/A	Available	Available, Rest Timer	Different Note 2

Items	New Device	Primary Predicate Device (K171685) Med4 Elite™	Secondary Predicate Device (K193550) Therm-X	Comparison
Pre-programmed cycles (Quick Picks)	Available, the device allows user to setup default settings for heat, cold and compression therapy.	Available, Med4 Elite™ allows user to setup default settings for heat, cold, contrast and compression therapy.	Available	Same
Dimensions	38×27.7×53cm	32.5" L x 24.75" W x 43"H (83 cm L x 63 cm W x 109cm H)	15" L x 10.5" W x 9" H	Different Note 4
Weight	16.5kg	172 lbs (78 kg)	15 lbs. when full of coolant	
Chilling Mechanism	Thermoelectric	Vapor compression	Thermoelectric	Same
Heating Mechanism	Thermoelectric	Resistance heaters	Thermoelectric	Same
Reservoir Fluid Capacity	Max 550ml (operation)	Heat reservoir: 1 gallon (3.8 L) Cold reservoir: 1 gallon (3.8 L)	650 mL	Different Note 5
User Interface	LED screen, touch buttons	Touch Screen	Touch Screen	Different Note 6
Recommended Coolant	Distilled Water	Distilled Water	90% Distilled Water, 10% Isopropyl Alcohol	Same
Line Voltage	100-240 VAC	100-240 VAC	100-240 VAC	Same
Line Frequency	50/60 Hz	50/60 Hz	50/60 Hz	Same
Electrical Safety Standards	IEC 60601-1	ANSI/AAMI ES60601-1:2005/(R) 2012 CAN/CSA C22.2 No. 60601- 1:2014 Type B	ANSI/AAMI ES60601-1:2005/(R)2012 CAN/CSA C22.2 No. 60601-1:2014 Type B IEC 60601-1-2	SE
Operating Temperature	10℃~27℃	50°F - 90°F (10°C – 32°C)	60°F – 80°F (16°C – 27°C)	Different Note 7
Storage Temperature	1℃~ 50℃	33°F - 122°F (1°C to 50 °C)	33°F – 122°F (1°C - 50°C)	Same
Operating Humidity	30%~90% Non-condensing	30 to 90%, Non-condensing	Below 60% Noncondensing	Same
Storage Humidity	10%~90%	10 to 95%, Non-condensing	Below 60% Noncondensing	Different Note 7
Operating Atmospheric Pressure	0-3,000m	0 – 9,842 Ft (0 – 3,000 m)	700 hPa – 1060 hPa (corresponds to a max. elevation of 9,842 ft. 6 in	Same

Items	New Device	Primary Predicate Device (K171685) Med4 Elite™	Secondary Predicate Device (K193550) Therm-X	Comparison
			(3000 m))	
Types of Cuffs	Various anatomical cuffs in single size for: Universal cuff Elbow cuff Hand/wrist cuff Back cuff Hip cuff Ankle cuff Thigh cuff Left shoulder cuff Right shoulder cuff	Various anatomical Wraps in different sizes for: Straight Knee, Articulated Knee, Elbow, Ankle, Shoulder, Back, Hip Groin, Hand-Wrist, Flexed Elbow, Half-leg boot	Various anatomical thermal garments for: Back, Elbow, Shoulder, Knee, Ankle, Hip. DVT Garments: Calf and Foot	Different Note 8
Cuff Material	Surface of cuff and hose: Nylon, reusable	70 Denier nylon Silcryn (hose covering)	Thermal garment, reusable (multi patient) – 30 denier nylon coated in urethane Thermal garment, disposable (single patient) – 200 denier nylon coated in urethane DVT – 200 denier nylon coated in urethane	Different Note 9
Multi-Patient Use or Single Patient Use Cuffs	Single-Patient Use Available	Multi-Patient Use	Multi-Patient Use and Single-Patient Use Available	Different Note 10
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-12	Cytotoxicity testing per ISO 10993-5 Sensitization testing per ISO 10993-10 Irritation testing per ISO 10993-10	Different Note 9
Sterility	Non-sterile only	Provided non-sterile only	Non-sterile only	Same

Substantial Equivalence Discussion

Note 1: Treat Time
The Heat Therapy Treatment Time, Cold Therapy Treatment Time and Compression Therapy Treatment Time are different from the primary predicate device and the reference device. The maximum treat time is not beyond the time of the predicate device and the reference device, only the set range or increment and default is different. The treat time is adjustable by professionals according to therapy plan. The subject has more flexibility in the set up; thus providing the clinician more options. Clinical skin temperature testing on healthy subjects at the minimum temperature setting did not cause thermal damage to the skin. Therefore, the difference between the subject and predicate devices do not raise safety and effectiveness issues.

Note 2: Contrast Therapy and “Snooze” Function
The subject device has no Contrast Therapy and “Snooze” Function. If the patient has to need the Contrast Therapy and “Snooze” Function therapy, the professionals may operate the device with multiple steps operation manually. The difference between the subject and predicate devices do not raise safety and effectiveness issues.

Note 3: Heat Reservoir Temperature Range and Cold Reservoir Temperature Range
The subject device has a higher minimum heat reservoir set point than the primary predicate device, and the same maximum heat reservoir set point. The range is within the range of the primary predicate device. The minimum set point is higher than the primary predicate device. Clinical skin surface temperature testing on healthy subjects at the highest temperature setting for heat and at lowest temperature setting for cold did not cause thermal or cold damage to the skin; thus no new safety issue. Therefore, the difference does not raise any safety or effectiveness issues.

Note 4: Weight and Dimensions
After comparison with the previously declared device, we believe that the weight and the dimension of subject device could be safe and effective during normal use for this type of device. It is lighter and smaller than the primary predicate device because of one fluid reservoir. Therefore, the difference does not raise any safety or effectiveness issues.

Note 5: Reservoir Fluid Capacity
The Reservoir Fluid Capacity is different from the primary predicate device and the reference device. The Fluid Capacity is smaller than one of primary predicate device. The heat and cold temperature of the Reservoir is test. Clinical skin temperature testing on healthy subjects at the minimum temperature setting did not cause thermal/cold damage to the skin.
Therefore, the difference between the subject and predicate devices do not impact safety and effectiveness.

Note 6: User Interface
The user interface is LED screen and touch buttons not touch screen of the primary predicate device and the reference device. The display function and button operation function testing is passed.
Therefore, the difference does not raise any safety or effectiveness issues.

Note 7: Operating Temperature
The subject device works in a lower temperature environment than primary predicate for the maximum temperature but lower than reference predicate for minimum temperature. The subject device is more than adequate for routine indoor use. The performance testing under operation temperature is passed.
Therefore, the difference does not raise any safety or effectiveness issues.

Note 8: Types of Cuffs
Although the Types of Cuffs is different with primary predicate device, however, the main use types (Elbow, Ankle, Shoulder, Back, Hip, Hand-Wrist, leg) and sizes are substantially equivalent. The subject device has Universal cuff which can use on Knee or limbs providing one option.

Therefore, it is considered that the difference between the subject and predicate devices does not impact safety and effectiveness.

Note 9: Cuff Materials
The cuff is nylon which is widely used in daily life. A layer of clothing between skin and the cuff is preferred during use in the user manual. Therefore, these differences do not impact safety and effectiveness.

Note 10: Multi-Patient Use or Single Patient Use Cuffs
The cuff of the subject device is used for single user. It may reduce the risk of cross infection because of Single-Patient Use. Therefore, the difference does not raise any safety or effectiveness issues.

These different technological characteristics of the subject devices do not raise different questions of safety and effectiveness. Thus, the subject device is Substantially Equivalent (SE) to the predicate devices which is legally marketed in US.

7 Non-Clinical Test Summary

The following performance data were provided in support of the substantial equivalence determination.

1) Biocompatibility Testing

Some components of the Hot and Cold Compression System (Mode: A02-C-032) are patient contacting such that the biocompatibility evaluation conformed to guidance document in accordance with the “Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing Within a Risk Management Process, Document Issued on September 8, 2023”, as recognized by FDA.

2) Electrical Safety and Electromagnetic Compatibility

Electrical safety and EMC testing was performed and passed, the following standards:

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

3) Performance-Bench

The device has been tested for accuracy of time and pressure control, accuracy of temperature control, seam strength testing, appearance testing, service life and software failure mode testing to verify the proper operation of the system. Test and verification results indicate that the device conforms to its predetermined specifications and operates within safety limits.

4) Software Verification and Validation

Software documentation consistent with Basic Documentation Level was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

5) Sterilization/Shelf Life/Cleaning & Disinfection

The Hot and Cold Compression System (Mode: A02-C-032) components (Main Unit, connector hoses, drain hoses) are provided non- sterile and do not need and cannot be sterilized. These components are not patient contacting. They are only contacted by the health care professional for setting up therapy. The unit is not intended for use in a sterile environment. Cleaning and disinfection instructions for the non-patient contacting components are given in the User Manual. The impact of repeated use of these cleaning/disinfecting materials over the expected life of the main unit has been validated.

The cuffs are intended for patient contacting. They are provided non-sterile and not intended to be user sterilized. Cleaning and disinfection instructions are provided for single-patient use cuffs. Such cleaning and disinfection instructions have been validated.

Neither The device components nor all the cuffs have a definitive shelf life based on packaging or time. Expected life is based on frequency of use and continued functional performance. The use life test has confirmed the safe use and disinfection of the cuffs for the duration of the cuff's life without evidence of deterioration of the cuff due to cleaning and/or disinfection.

6) Animal Data

No animal studies were necessary for the subject device.

7) Skin temperature study

The device was tested for the worst-case use scenario on healthy volunteer human subjects who provided informed consent. A minimum skin temperature and the maximum skin temperature were measured and has been included in the product labeling. The results are summarized in Table below:

Maximum Temperature	Skin temperature measured as high as 44.2 °C (45 °C) when set to maximum Heat Reservoir set point
Minimum Temperature	Skin temperature measured as low as 5.1 °C (4 °C) when set to minimum Cold Reservoir set point

Based on these results, it has been concluded that the temperature limits of the subjected device do not cause any thermal damage to the skin. The studies demonstrated that there are no safety issues created by the device and that the device is as safe and effective as the predicate devices.

8 Clinical Data

Not needed for this 510(k).

9 Conclusions

The subject device Hot and Cold Compression System (Mode: A02-C-032) is respectively substantially equivalent to the predicate device (Med4 Elite) manufactured by Cool Systems, Inc. (K171685) and reference device (Therm-X) manufactured by Zenith Technical Innovations (K193550).