June 21, 2024

Zenith Technical Innovations
% Rita King
Chief Executive Officer
MethodSense, Inc.
1 Copley Parkway
Suite 130
Morrisville, North Carolina 27560

Re: K240125
Trade/Device Name: Therm-X (Home); Therm-X (AT)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW, IRP, ILO
Dated: May 23, 2024
Received: May 24, 2024

Dear Rita King:

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

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

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

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

Sincerely,

Nicole M. Gillette -S

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support, Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Reprocessed Single-Use Device Models Included in Clearance:

Device Model	Device Name	Original Manufacturer
TX0107	Calf DVT Garment	ZTI
TX0106	Foot DVT Garment	ZTI
TX0102	Knee Thermal Garment	ZTI
TX0105	Back Thermal Garment	ZTI
TX0101	Shoulder Thermal Garment	ZTI
TX0110	XL Shoulder Garment	ZTI
TX0104	Ankle Thermal Garment	ZTI
TX0103	Elbow Thermal Garment	ZTI
TX0108	Hip Thermal Garment	ZTI
TX0111	Half-leg Thermal Garment	ZTI
TX0112	Hand Thermal Garment	ZTI

DVT – Deep Vein Thrombosis
ZTI – Zenith Technical Innovations

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

Submission Number *(if known)*

K240125

Device Name

Therm-X (Therm-X Home and Therm-X AT)

Indications for Use *(Describe)*

Therm-X (Therm-X Home and Therm-X AT) combines cold, heat contrast, and compression therapy. Therm-X (Therm-X Home and Therm-X AT) 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. The Therm-X (Therm-X Home and Therm-X AT) is also intended for treatment of disorders associated with vascular or lymphatic insufficiency, such as lymphedema and chronic venous insufficiency (CVI).

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.

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.

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

Zenith Technical Innovations K240125

This 510(k) Summary is in conformance with 21 CFR 807.92

Submitter: Zenith Technical Innovations, LLC. (Zenith)
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MethodSense, Inc.
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Company Contact: Greg Binversie
Chief Technical Officer

Date Prepared: June 21, 2024

Device Name and Classification

Trade Name: Therm-X
Common Name: Sleeve, Limb, Compressible
Classification: Class II
Regulation Number: 21 CFR 870.5800 - Compressible limb sleeve
Classification Panel: Cardiovascular
Product Code: JOW, IRP, ILO

Predicate Devices

Trade Name:	Therm-X	VascuTherm™
Common Name:	Heat and/or Cold and Compression Therapy	Intermittent, External Pneumatic Compression Device
510(k) Submitter / Holder:	Zenith Technical Innovations, LLC. (Zenith)	ThermoTek, Inc.
510(k) Number:	K231912	K061866
Classification:	Class II	Class II
Regulation Number:	890.5650, Powered Inflatable tube massager	870.5800 - Compressible limb sleeve
Classification Panel:	Physical Medicine	Cardiovascular
Product Code:	IRP, ILO, JOW	JOW

The predicate devices have not been subject to a design-related recall.

Device Description

Therm-X is an AC powered, software-controlled multimodality device, designed to be used in a clinical or home-use setting, and under the direction, prescription, or supervision of a licensed healthcare professional. The device is available in two configurations: Therm-X Home and Therm-X AT.

Therm-X (Therm-X Home and Therm-X AT) features iceless cold therapy, heat therapy, and contrast (alternating heat and cold) therapy. The Therm-X Home system also provides DVT prophylaxis therapy and continuous therapy for users who wish to receive treatment over an extended period of time.

Therm-X (Therm-X Home and Therm-X AT) consists of various reusable inflatable wraps for thermal treatment of the back, elbow, hand/wrist, shoulder, ankle, hip, lower leg, or knee and DVT prophylactic treatment applied to the foot or calf. Multi-patient use garments are available for all anatomical areas that can be cleaned and disinfected in between uses to be reused for different patients. Single-patient use garments are available for thermal treatment of the back, hand/wrist, shoulder, neck, ankle, hip, and knee and can be disposed of after patient treatment is concluded. The thermal garments are flexible coolant circulating garments that apply to the body to deliver cold, heat, or contrast therapy in combination with or without pneumatic compression. The foot and calf DVT prophylactic garments apply pneumatic compression alone and are intended for use by the Therm-X Home system only.

Therm-X (Therm-X Home and Therm-X AT) is controlled by an intuitive touch screen computer interface, allowing the user to manage the therapy modalities as well as easily adjust and monitor treatment times, temperature, and compression settings. Therm-X AT and Therm-X Home models provide an optional password protection feature that allows for a user to use only stored cycles, giving health care providers an ability to ensure compliance to a chosen cycle. The device also provides functionality to allow the health care provider to assign a date at which the user will be able to access a second stored cycle instead of the first. The Therm-X device also allows users to change treatment pressure and temperatures to less extreme therapies (e.g. changing a warm cycle to a lower warm temperature or changing a cold cycle to a higher cold temperature).

Therm-X (Therm-X Home and Therm-X AT) is approximately 15 lbs. when filled with coolant and has a handle placed on the top of the device. It has a centralized coolant reservoir accessible through a cap located at the back of the device that supplies its coolant and radiator systems. The reservoir, pumps, fans, circuit board, and other components of the Therm-X are located inside a covered enclosure made out of plastic and metal components, accessible only using a specialized tool.

Indications for Use

Therm-X (Therm-X Home and Therm-X AT) combines cold, heat, contrast, and compression therapy. Therm-X (Therm-X Home and Therm-X AT) 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 (Therm-X Home and Therm-X AT) is also intended for treatment of disorders associated with vascular or lymphatic insufficiency, such as lymphedema and chronic venous insufficiency (CVI).

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.

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.

Risk Analysis Method

Therm-X (Therm-X Home and Therm-X AT) was assessed to determine the risks to health associated with the updated indications for use and evaluate risks related to safety, effectiveness, and usability. A risk analysis was conducted in accordance with ISO 14971:2019, Medical devices -- Application of risk management to medical devices. No additional risks were associated with the addition of treating disorders associated with vascular or lymphatic insufficiency such as lymphedema and chronic venous insufficiency (CVI) to the indications for use.

Substantial Equivalence

Therm-X (Therm-X Home and Therm-X AT) is substantially equivalent to Therm-X (K231912) by Zenith Technical Innovations, LLC. (Zenith) and VascuTherm™ (K061866) by ThermoTek, Inc. currently on the market.

Therm-X (Therm-X Home and Therm-X AT) has the same intended use as the Therm-X (K231912) and VascuTherm™ (K061866) and uses equivalent overall design and operating principals as the Therm-X predicate device (K231912).

The table below provides a detailed comparison of Therm-X (Therm-X Home and Therm-X AT) to the predicate devices:

Detailed Comparison of the Subject and Predicate Devices

Characteristic	Therm-X *Subject Device*	Therm-X (K231912) *Primary Predicate*	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) *Secondary Predicate*	Comparison
Indications for Use	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 (Therm-X Home and Therm-X AT) is also intended for treatment of disorders associated with vascular or lymphatic insufficiency, such as lymphedema and chronic venous insufficiency (CVI). Therm-X Home systems also provide DVT therapy. Therm-	Therm-X (Therm-X Home and Therm-X AT) combines cold, heat, contrast, and compression therapy. Therm-X is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain for which cold and compression are indicated. It is intended to treat post traumatic and post-surgical medical and/or surgical conditions for which localized thermal therapy (hot or cold) are indicated. Therm-X Home systems also provide DVT therapy. Therm-X Home systems with DVT therapy are intended to reduce the risk of the formation of deep venous thrombosis (DVT) by aiding blood flow back to the heart via lower extremity limb compression.	Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema. Reduction of Edema associated with soft tissue injuries such as bums, postoperative edema, and ligament sprains. Localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions. Decrease the risk of deep venous thrombosis (DVT). Aids the blood flow back to the heart.	Therm-X (subject device) indications for use are identical to Therm-X (K231912) with the only difference being that the Therm-X (subject device) also indicates that the device may be used for treatment of disorders associated with vascular or lymphatic insufficiency, such as lymphedema and CVI. The indications for use for the treatment of disorders associated with vascular or lymphatic insufficiency, such as lymphedema and CVI of Therm-X (subject device) are equivalent to the VascuThermTM (K061866) indications for treatment of these same disorders.

Characteristic	Therm-X ***Subject Device***	Therm-X (K231912) ***Primary Predicate***	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) ***Secondary Predicate***	Comparison
	X Home systems with DVT therapy are intended to reduce the risk of the formation of deep venous thrombosis (DVT) and 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.	Therm-X (Therm-X Home and Therm-X AT) is intended to be used by, or on the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, athletic training settings, and home settings.	Treat and assist healing of cutaneous ulceration (wounds), reduce would healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications.	
Intended Users	Health Care Professionals and lay users (under prescription)	Health Care Professionals and lay users (under prescription)	Health Care Professionals and lay users (under prescription	Therm-X (subject device) is identical to Therm-X (K231912) and VascuTherm™ (K061866).
Number of Patients that can be treated at one time	Two	Two	One	Therm-X (subject device) is identical to Therm-X (K231912).

Characteristic	Therm-X ***Subject Device***	Therm-X (K231912) ***Primary Predicate***	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) ***Secondary Predicate***	Comparison
Two Programmable Cycles	Configuration of two programmable cycles are available for all Therm-X Models	Configuration of two programmable cycles are available for all Therm-X Models	Not Available.	Therm-X (subject device) is identical to Therm-X (K231912).
Continuous Treatment Cycle	Available on Therm-X Home	Available on Therm-X Home	Available.	Therm-X (subject device) is identical to Therm-X (K231912) and VascuTherm™ (K061866).
Heat Therapy	Default: 105°F, 107°F, 110°F Custom: 105°F – 110°F Default, continuous: 105°F, 107°F Custom, continuous: 105°F – 107°F	Default: 105°F, 107°F, 110°F Custom: 105°F – 110°F Default, continuous: 105°F, 107°F Custom, continuous: 105°F – 107°F	105°F	Therm-X (subject device) is identical to Therm-X (K231912) and equivalent to VascuTherm™ (K061866). .
Cold Therapy	Default: 34°F, 45°F, 55°F Custom: 34°F – 55°F Default, continuous: 40°F, 45°F, 50°F Custom, continuous: 40°F – 50°F	Default: 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	43 – 49°F	Therm-X (subject device) is identical to Therm-X (K231912).

Characteristic	Therm-X ***Subject Device***	Therm-X (K231912) ***Primary Predicate***	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) ***Secondary Predicate***	Comparison
Edema Pressure Levels	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: Lite (5 mm Hg) Low (20 mm Hg) Medium (45 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: Lite (5 mm Hg) Low (20 mm Hg) Medium (45 mm Hg)	Available in three levels: Low (15 mmHg) Medium (30 mmHg) High (50 mmHg)	Therm-X (subject device) is identical to Therm-X (K231912).
Static or Intermittent Pressure	Both	Both	Both	Therm-X (subject device) is identical to Therm-X (K231912) and VascuTherm™ (K061866)..
DVT Only	Available for Therm-X Home Model	Available for Therm-X Home Model	Available	Therm-X (subject device) is identical to Therm-X (K231912) and VascuTherm™ (K061866).
DVT Pressure	Calf: 50 – 70 mmHg Foot: 90 – 130 mmHg	Calf: 50 – 70 mmHg Foot: 90 – 130 mmHg	Calf: 45 mmHg Foot: 100 mmHg	Therm-X (subject device) is identical to Therm-X (K231912).

Characteristic	Therm-X ***Subject Device***	Therm-X (K231912) ***Primary Predicate***	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) ***Secondary Predicate***	Comparison
Cycle Length (for Heat, Cold, and Compression)	Default: 10 or 20 minutes Custom: 3 – 40 minutes Continuous: 10 – 40 minutes active, 30-60 minutes rest	Default: 10 or 20 minutes Custom: 3 – 40 minutes Continuous: 10 – 40 minutes active, 30-60 minutes rest	Default: 30 minutes (presumed – not clearly stated in User Manual) Continuous: 30 minutes (presumed not clearly stated in User Manual) Compression: Unknown	Therm-X (subject device) is identical to Therm-X (K231912).
Contrast Therapy	Available for Therm-X AT Model only Heat: 105°F Cold: 38°F	Available for Therm-X AT Model only Heat: 105°F Cold: 38°F	Available Heat: 10 minutes Cold: 20 minutes Note: Contrast therapy is available only in VascuTherm™ 5	Therm-X (subject device) is identical to Therm-X (K231912).
Cycle Length (for Contrast Therapy)	Heat: 3-10 minutes Cold: 3-10 minutes Total treatment: 6-60 minutes	Heat: 3-10 minutes Cold: 3-10 minutes Total treatment: 6-60 minutes	30 minutes (presumed not clearly stated in User Manual)	Therm-X (subject device) is identical to Therm-X (K231912).
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.	30 minutes (presumed not clearly stated in User Manual)	Therm-X (subject device) is identical to Therm-X (K231912).
Edema Compression and DVT Compression at the same time	Available Edema Compression (Lite, Low, Medium, High) must be combined with cold, heat, or contrast therapy	Available Edema Compression (Lite, Low, Medium, High) must be combined with cold, heat, or contrast therapy	Available	Therm-X (subject device) is identical to Therm-X (K231912) and VascuTherm™ (K061866).

Characteristic	Therm-X ***Subject Device***	Therm-X (K231912) ***Primary Predicate***	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) ***Secondary Predicate***	Comparison
DVT Inflation and Deflation	DVT Inflation: Up to 120 seconds DVT Deflation: Up to 30 seconds	DVT Inflation: Up to 120 seconds DVT Deflation: Up to 30 seconds	Cycle time Inflation: 20 seconds, Deflation: 40 sec	Therm-X (subject device) is identical to Therm-X (K231912).
Power Down	Available	Available	Available	Therm-X (subject device) is identical to Therm-X (K231912) and VascuTherm™ (K061866).
Password Protection	Available	Available	VascuTherm™ 5: The therapy profiles can be locked. Only healthcare professionals can unlock therapy profiles and just settings. VascuTherm™ 4: Set temperature can be preprogrammed and locked.	Therm-X (subject device) is identical to Therm-X (K231912).
Store Cycle Usage Data	Available	Available	Was not able to determine from publicly available information.	Therm-X (subject device) is identical to Therm-X (K231912).
Dimensions	15” L x 10.5” W x 9” H	15” L x 10.5” W x 9” H	VascuTherm™ 5 13.2” H x 12.00” D x 6.6” W (335 mm H x 305 mm D x 167 mm W) VascuTherm™ 4: 9.88” H x 8.75” D x 9.81” W (251 mm H x 222 mm D x 249 mm W)	Therm-X (subject device) is identical to Therm-X (K231912).

Characteristic	Therm-X *Subject Device*	Therm-X (K231912) *Primary Predicate*	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) *Secondary Predicate*	Comparison
Weight	15 lbs. when full of coolant	15 lbs. when full of coolant	VascuTherm™ 5: 18.75 lbs (8.5 kg) VascuTherm™ 4: 9.5 lbs	Therm-X (subject device) is identical to Therm-X (K231912).
Chilling Mechanism	Thermoelectric	Thermoelectric	Thermoelectric	Therm-X (subject device) is identical to Therm-X (K231912) and VascuTherm™ (K061866).
Heating Mechanism	Thermoelectric	Thermoelectric	Thermoelectric	Therm-X (subject device) is identical to Therm-X (K231912) and VascuTherm™ (K061866).
Reservoir Fluid Capacity	650 mL	650 mL	Vascutherm™ 5: 320 mL VascuTherm™ 4: 250 mL	Therm-X (subject device) is identical to Therm-X (K231912).
User Interface	Touch Screen	Touch Screen	Touch Screen	Therm-X (subject device) is identical to Therm-X (K231912).
Recommended Coolant	90% Distilled Water, 10% Isopropyl Alcohol	90% Distilled Water, 10% Isopropyl Alcohol	90% Distilled Water, 10% Isopropyl Alcohol	Therm-X (subject device) is identical to Therm-X (K231912) and VascuTherm™ (K061866).

Characteristic	Therm-X *Subject Device*	Therm-X (K231912) *Primary Predicate*	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) *Secondary Predicate*	Comparison
Line Voltage	100-240 VAC	100-240 VAC	100-240 VAC	Therm-X (subject device) is identical to Therm-X (K231912) and VascuTherm™ (K061866).
Line Frequency	50/60 Hz	50/60 Hz	50/60 Hz	Therm-X (subject device) is identical to Therm-X (K231912) and VascuTherm™ (K061866).
Electrical Safety Standards	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 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2 UL 60601 Safety Standards Type B	Therm-X (subject device) is identical to Therm-X (K231912).
Operating Temperature	40°F – 130°F (4.4°C – 54.4°C)	40°F – 130°F (4.4°C – 54.4°C)	VascuTherm™ 4: 60-80°F (16°C - 27°C) VascuTherm™ 5: 50-80°F (10°C - 27°C)	Therm-X (subject device) is identical to Therm-X (K231912).

Characteristic	Therm-X *Subject Device*	Therm-X (K231912) *Primary Predicate*	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) *Secondary Predicate*	Comparison
Storage Temperature	33°F – 122°F (1°C - 50°C)	33°F – 122°F (1°C - 50°C)	40-105°F	Therm-X (subject device) is identical to Therm-X (K231912).
Operating Humidity	Below 60% Non-condensing	Below 60% Non-condensing	Below 60% Non-condensing	Therm-X (subject device) is identical to Therm-X (K231912) and VascuTherm™ (K061866)..
Storage Humidity	Below 60% Non-condensing	Below 60% Non-condensing	10%-95% Non-condensing	Therm-X (subject device) is identical to Therm-X (K231912).
Operating Atmospheric Pressure and Altitude	700 hPa – 1060 hPa (corresponds to a max. elevation of 9,842 ft. 6 in (3000 m))	700 hPa – 1060 hPa (corresponds to a max. elevation of 9,842 ft. 6 in (3000 m))	No information available.	Therm-X (subject device) is identical to Therm-X (K231912).
Types of Garments	Various anatomical thermal garments for: Back, Elbow, Hand, Shoulder, XL Shoulder, Knee, Half-Leg, Ankle, Hip, Neck. DVT Garments: Calf and Foot	Various anatomical thermal garments for: Back, Elbow, Hand, Shoulder, XL Shoulder, Knee, Half-Leg, Ankle, Hip, Neck. DVT Garments: Calf and Foot	Various anatomical wraps for: Arm, Wrist, Back, Face, Foot, Ankle, Hip, Knee, Shoulder, Torso, Half Arm, Head, Half-Leg, Full Leg DVT Wraps: Calf and Foot	Therm-X (subject device) is identical to Therm-X (K231912).

Characteristic	Therm-X ***Subject Device***	Therm-X (K231912) ***Primary Predicate***	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) ***Secondary Predicate***	Comparison
Patient Contacting Material	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 Butterfly Garment Elastic Strap – Lycra/Spandex, Polyester, Nylon	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	Thermal wrap - 200 Denier Nylon Oxford DVT wrap – DuPont Softesse® Medical Fabric (non-latex, non-woven)	Therm-X (subject device) is identical to Therm-X (K231912) with the exception that Therm-X (subject device) includes new elastic straps for a garment that are comprised of Lycra/Spandex, Polyester, and Nylon. These additional patient contacting materials do not raise questions of safety and effectiveness as they are recognized as commonly used medical grade materials with a long history of safe use in legally marketed medical devices.
Multi-Patient Use or Single-Patient Use Wraps	Multi-Patient Use and Single-Patient Use Available	Multi-Patient Use and Single-Patient Use Available	Single-Patient Use	Therm-X (subject device) is identical to Therm-X (K231912).

Characteristic	Therm-X ***Subject Device***	Therm-X (K231912) ***Primary Predicate***	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) ***Secondary Predicate***	Comparison
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	No information available.	Therm-X (subject device) is identical to Therm-X (K231912).
Sterile/Non-Sterile	Non-sterile only	Non-sterile only	Sterile and non-sterile	Therm-X (subject device) is identical to Therm-X (K231912).
Cleaning Disinfection Validation of Labeling	Yes – for Multi-patient use reusable wraps	Yes – for Multi-patient use reusable wraps	No information available.	Therm-X (subject device) is identical to Therm-X (K231912).
Human Factors Testing to confirm intended users have found instructions for cleaning and disinfection easy to use	Yes – for Multi-patient use reusable wraps	Yes – for Multi-patient use reusable wraps	No information available.	Therm-X (subject device) is identical to Therm-X (K231912).
Expected Life of garments	Based on frequency of use and continued functional performance	Based on frequency of use and continued functional performance	No information available.	Therm-X (subject device) is identical to Therm-X (K231912).

Characteristic	Therm-X ***Subject Device***	Therm-X (K231912) ***Primary Predicate***	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) ***Secondary Predicate***	Comparison
Validation of repeated cleaning and disinfection for reusable garments	Yes – for Multi-patient use reusable wraps	Yes – for Multi-patient use reusable wraps	No information available.	Therm-X (subject device) is identical to Therm-X (K231912).

In this submission, Zenith has added additional indications for use for the treatment of disorders associated with vascular or lymphatic insufficiency, such as lymphedema and chronic venous insufficiency (CVI). Therm-X (Therm-X Home and Therm-X AT) with these additional indications is substantially equivalent to the identified predicate devices, Therm-X (K231912) and VascuTherm™ (K061866).

Testing

No additional testing has been performed for the additional indications for use. Therm-X (Therm-X Home and Therm-X AT) and Therm-X software were previously verified and validated in accordance with documented Verification & Validation plans and protocols to ensure conformance with established performance criteria. See below for the type of tests performed.

Performance – Bench

Therm-X (Therm-X Home and Therm-X AT) has been tested for performance to verify the proper operation of the system. Test and verification results indicate that Therm-X (Therm-X Home and Therm-X AT) conforms to its predetermined specifications and operates within safety limits.

Electromagnetic Compatibility / Electrical Safety:

Electromagnetic Compatibility / Electrical Safety testing was performed in accordance with 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 compatibility - Requirements and tests Verification results indicated that the device is safe
- IEC 60601-1-11: Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Biocompatibility:

The Therm-X (Therm-X Home and Therm-X AT) garment patient contacting materials were verified in accordance with the following standards:

- ISO 10993-1: 2009, 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

Verification results indicated that the materials comply with the standard.

Cleaning, Disinfection & Shelf Life Testing:

Therm-X (Therm-X Home and Therm-X AT) garments are intended for use over intact skin or sterile dressings only. They are provided non-sterile and not intended to be user sterilized. Cleaning and disinfection instructions are provided for multi-patient use garments within each garment IFU. Such cleaning and disinfection instructions have been validated. The Therm-X (Therm-X Home and Therm-X AT) System components and garments do not have a definitive shelf life based on packaging or time. Expected life is based on frequency of use and continued functional performance. Durability accelerated aging test has been performed and has confirmed the safe use and disinfection of a Therm-X (Therm-X Home and Therm-X AT) garment for the duration of the garment's life without evidence of deterioration of the garment due to cleaning and/or disinfection.

Software Validation:
Zenith has conducted software validation testing on the Therm-X software and confirmed that Therm-X software meets its performance requirements and specifications. Software Validation has been completed according to an established Validation procedure and FDA Guidance document requirements for Enhanced Documentation Level and Industry Standards:

- General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 11, 2002
- Guidance for the Content of Premarket Submissions for Device Software Functions, June 14, 2023

Clinical Testing:
IRB approved studies have been performed to measure the lowest skin temperature the Therm-X (Therm-X Home and Therm-X AT) device can generate. As required by the FDA guidance for heating and cooling devices, Therm-X (Therm-X Home and Therm-X AT) was tested for worst case conditions on healthy volunteer human subjects who provided informed consent. A minimum skin temperature of 40°F was measured and has been included in the product labeling.

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

Human Factors / Usability:
Human Factors / Usability assessments have been performed in a simulated use environment to optimize the device design and support the safe use of Therm-X (Therm-X Home and Therm-X AT). Therm-X (Therm-X Home and Therm-X AT) has been found to be adequately safe and effective for the intended users, its intended uses and use environments. The results demonstrated that users can operate Therm-X (Therm-X Home and Therm-X AT) as safely and as effectively as the predicate devices.

Substantial Equivalence Conclusion

In conclusion, the intended use for Therm-X (Therm-X Home and Therm-X AT) is substantially equivalent to that of the predicate devices. Additionally, the technological characteristics comparison demonstrates that Therm-X (Therm-X Home and Therm-X AT) is substantially equivalent to the predicates, assuring that Therm-X (Therm-X Home and Therm-X AT) is as safe and effective as the predicate devices.

Conclusion

The 510(k) Pre-market Notification for Therm-X (Therm-X Home and Therm-X AT) contains adequate information and data to determine that Therm-X (Therm-X Home and Therm-X AT) is as safe and effective as the legally marketed predicate devices.