May 10, 2019

Zenith Technical Innovations
% Rita King
CEO
MethodSense, Inc.
1 Copley Parkway, Suite 410
Morrisville, North Carolina 27560

Re: K190854
Trade/Device Name: Therm-X
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP, ILO, JOW
Dated: April 1, 2019
Received: April 2, 2019

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 (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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek Pinto, PhD
Assistant Director
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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190854

Device Name
Therm-X

Indications for Use *(Describe)*

Therm-X (Therm-X Pro, Therm-X Pro Athlete, 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 Pro and Therm-X Pro Athlete systems also provide DVT therapy. Therm-X Pro and Therm-X Pro Athlete 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 Pro, Therm-X Pro Athlete 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 K190854

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

Submitter: Zenith Technical Innovations, LLC. (Zenith)
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Date Prepared: May 6, 2019

Device Name and Classification

Trade Name: Therm-X
Common Name: Heat and/or Cold and Compression Therapy
Classification: Class II
Regulation Number: 21 CFR 890.5650, Powered inflatable tube massager
Classification Panel: Physical Medicine
Product Code: IRP, ILO, JOW

Predicate Devices

Predicate:	Primary	Secondary	Secondary
Trade Name:	Therm-X	Med4 Elite™	VascuTherm™ (and NanoTherm™)
Common Name:	Heat and/or Cold and Compression Therapy	Heat and/or Cold and Compression Therapy	Intermittent, External Pneumatic Compression Device
510(k) Submitter / Holder:	Zenith Technical Innovations, LLC	CoolSystems, Inc.	ThermoTek, Inc.
510(k) Number:	K181149	K171685	K061866
Classification:	Class II	Class II	Class II
Regulation Number:	890.5650, Powered inflatable tube massager	890.5650, Powered Inflatable tube massager	870.5800, Compressible limb sleeve
Classification Panel:	Physical Medicine	Physical Medicine	Cardiovascular
Product Code:	IRP, ILO, JOW	IRP, ILO	JOW, ILO

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 three configurations: Therm-X Pro, Therm-X Pro Athlete and Therm-X AT.

Therm-X (Therm-X Pro, Therm-X Pro Athlete and Therm-X AT) features iceless cold therapy, heat therapy, and contrast (alternating heat and cold) therapy. Therm-X Pro and Therm-X Pro Athlete systems also provide DVT prophylaxis therapy.

Therm-X consists of various reusable inflatable wraps for thermal treatment of the back, elbow, shoulder, ankle, or knee and DVT prophylactic treatment applied to the foot or calf. The thermal garments are flexible coolant circulating garments that apply to the body to deliver cold, heat, or contrast therapy in combination with pneumatic compression. The Foot and calf DVT prophylactic garments apply pneumatic compression alone and are intended for use by Therm-X Pro and Therm-X Pro Athlete systems only.

Therm-X 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 Pro models provide an optional password protection feature that allows for a home user to use a stored cycle without being able to change it, 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.

Therm-X 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 system are located inside a covered enclosure made out of plastic and metal components, accessible only using a specialized tool.

Therm-X is a class II medical device per FDA classification and has been previously cleared by the FDA under K181149. The Therm-X single-patient use garments under K181149 have been changed to multi-patient use garments through the use of a low-level disinfection process. Based on the guidance “Guidance for Industry and Food and Drug Administration Staff: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling” (March 17, 2015), the Therm-X garments are considered reusable medical devices initially supplied as non-sterile to the user and requiring the user to process (i.e., disinfect) the device for initial use, as well as to reprocess the device after each use. The garments are considered non-critical devices in that they contact only intact skin and do no penetrate it. Therm-X garments may become contaminated with microorganisms and organic soil during patient care and such contamination may not be visible. To account for this contamination and to prevent patient harm when used with multiple patients, Zenith uses a low-level disinfection process for the Therm-X garments.

Indications for Use

The indications for use for the Therm-X system (K190854) have not changed since the device was cleared (K181149) and are as follows:

Therm-X (Therm-X Pro, Therm-X Pro Athlete, 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 Pro and Therm-X Pro Athlete systems also provide DVT therapy. Therm-X Pro and Therm-X Pro Athlete 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 Pro, Therm-X Pro Athlete 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 (including reusable garments) was assessed to determine the risks to health associated with the use of the device and evaluate risks related to safety, effectiveness, and usability. A risk analysis was conducted in accordance with ISO 14971:2007 and ISO14971:2012, Medical devices -- Application of risk management to medical devices. Several risks were assessed, including, but not limited to, device malfunction, allergic reaction, infection, and improper use.

Substantial Equivalence

Therm-X (K190854) is substantially equivalent to Therm-X by Zenith (K181149), Med4 Elite by Coolsystems, Inc. (K171685) and VascuTherm by ThermoTek, Inc. (K061866), currently on the market.

Therm-X (K190854) has the same indications for use as Therm-X (K181149).

Therm-X (K190854), Med4 Elite™ and VascuTherm™ all provide reusable garments.

Therm-X (K190854), Therm-X (K181149), Med4 Elite™ and VascuTherm™ provide non-sterile garments.

There are no differences in the technology between Therm-X (K190854) and Therm-X (K181149). The primary differences of the technology of the Therm-X device with the predicate devices are discussed below.

The following table provides side by side comparison of Therm-X with the predicate devices.

Detailed Comparison of the Subject and Predicate Devices

Characteristic	Therm-X (this submission - K190854)	Therm-X (K181149) Primary predicate	Med4 Elite™ (K171685) Secondary Predicate	VascuTherm™ (and NanoTherm™) (K061866) Secondary Predicate	Comparisons
Indications for Use	Therm-X (Therm-X Pro, Therm-X Pro Athlete, 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 Pro and Therm-X Pro Athlete systems also provide DVT	Therm-X (Therm-X Pro, Therm-X Pro Athlete, 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 Pro and Therm-X Pro Athlete systems also provide DVT therapy. Therm- X Pro and Therm-X Pro Athlete are intended to reduce the risk of the formation of deep venous thrombosis (DVT) by	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, licensed healthcare professionals in	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.	The indications for use of Therm-X (K190854) are identical to the primary predicate, Therm-X (K181149). The indications for use of Therm-X (K190854) are identical to the Med4 Elite™ with the only difference being that the Therm-X also provides DVT therapy and is being used in both professional and home settings. The indications for use of Therm-X (Therm-X Pro and Therm-X Pro Athlete) (K190854) are also identical to VascuTherm™ for DVT therapy with the only difference being that VascuTherm™ is not used in home settings.

Characteristic	Therm-X (this submission - K190854)	Therm-X (K181149) Primary predicate	Med4 Elite™ (K171685) Secondary Predicate	VascuTherm™ (and NanoTherm™) (K061866) Secondary Predicate	Comparisons
	therapy. Therm- X Pro and Therm-X Pro Athlete 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 Pro, Therm-X Pro Athlete 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.	aiding blood flow back to the heart via lower extremity limb compression. Therm-X (Therm-X Pro, Therm-X Pro Athlete 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.	rehabilitation facilities, outpatient clinics, and athletic training 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.	

Characteristic	Therm-X (this submission - K190854)	Therm-X (K181149) Primary predicate	Med4 Elite™ (K171685) Secondary Predicate	VascuTherm™ (and NanoTherm™) (K061866) Secondary Predicate	Comparisons
Intended Users	Health Care Professionals and lay users (under prescription)	Health Care Professionals and lay users (under prescription)	Health Care Professionals only (Prescription use)	Health Care Professionals only (Prescription use)	The intended users of Therm-X (K190854) are identical to the primary predicate, Therm-X (K181149). Therm-X (K190854) intended users are equivalent to the Med4 Elite™ and VascuTherm™ with the only difference being that the intended users for the Med4 Elite™ and VascuTherm do not include lay users in the home setting.
Number of Patients that can be treated at one time	One	One	Two	One	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149). Therm-X (K190854) is designed to treat one patient at a time and it is identical to the VascuTherm™.

Characteristic	Therm-X (this submission - K190854)	Therm-X (K181149) Primary predicate	Med4 Elite™ (K171685) Secondary Predicate	VascuTherm™ (and NanoTherm™) (K061866) Secondary Predicate	Comparisons
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	Not Available	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149).
Functions					
Heat Therapy	Default: 105, 107, 110°F Custom: 105°F – 110°F	Default: 105, 107, 110°F Custom: 105°F – 110°F	95 – 113°F (35 – 45°C)	105°F	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149). The Therm-X (K190854) Heat Therapy Temperature Range is equivalent to the Med4 Elite™.
Cold Therapy	Default: 34, 45, 55°F Custom: 34 – 55°F	Default: 34, 45, 55°F Custom: 34 – 55°F	38 – 60°F (3.33 – 15.56°C)	43 – 49°F	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149). The Therm-X (K190854) temperature range for Cold Therapy is equivalent to the Med4 Elite™. The Therm-X (K190854) maximum temperature range for Cold Therapy is equivalent to Med4Elite™.

Characteristic	Therm-X (this submission - K190854)	Therm-X (K181149) Primary predicate	Med4 Elite™ (K171685) Secondary Predicate	VascuTherm™ (and NanoTherm™) (K061866) Secondary Predicate	Comparisons
Edema Pressure Levels	Available in three levels Low (20 mm Hg) Medium (45 mm Hg) High (70 mm Hg)	Available in three levels Low (20 mm Hg) Medium (45 mm Hg) High (70 mm Hg)	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 three levels (general) Low (15 mm Hg) Medium (30 mm Hg) High (50 mm Hg)	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149). The edema pressure levels for Therm-X (K190854) are equivalent to the pressure levels for the Med4Elite™. Therm-X (K190854) like VascuTherm™ provides constant values for Low, Medium and High compression.
DVT Only	Available for Therm-X Pro Athlete and Therm-X Pro Models.	Available for Therm-X Pro Athlete and Therm-X Pro Models.	Not Available	Available	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149). Therm-X Pro Athlete and Therm-X Pro Models (K190854) are identical to VascuTherm™.

Characteristic	Therm-X (this submission - K190854)	Therm-X (K181149) Primary predicate	Med4 Elite™ (K171685) Secondary Predicate	VascuTherm™ (and NanoTherm™) (K061866) Secondary Predicate	Comparisons
DVT Pressure	Calf: 50 - 70 mm Hg Foot: 100 – 130 mm Hg	Calf: 50 - 70 mm Hg Foot: 100 – 130 mm Hg	Not available	Calf: 45 mm Hg Foot: 100 mm Hg	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149). Therm-X (K190854) has a higher range for Foot and Calf DVT pressures than the VascuTherm™ and has equivalent DVT pressure to reference predicate, IC-BAP-DL BioArterial Plus Arterial Blood Flow Enhancement System (K131327).
Cycle Length (for Heat, Cold and Compression)	Heat: 20, 30, or 40 minutes Cold: 20, 30, or 40 minutes Compression: 20, 30, or 40 minutes	Heat: 20, 30, or 40 minutes Cold: 20, 30, or 40 minutes Compression: 20, 30, or 40 minutes	Heat: 5 to 30 minutes, 15 minutes default Cold: 5 to 60 minutes, 15 minutes default Compression: 5 to 60 minutes, 15 minutes default	Heat: 30 minutes (presumed – not clearly stated in User Manual) Cold: 30 minutes (presumed not clearly stated in User Manual) Compression: Unkown	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149). The Therm-X (K190854) Cycle length for Heat, Cold and Compression is equivalent to Med4 Elite™.

Characteristic	Therm-X (this submission - K190854)	Therm-X (K181149) Primary predicate	Med4 Elite™ (K171685) Secondary Predicate	VascuTherm™ (and NanoTherm™) (K061866) Secondary Predicate	Comparisons
Contrast Therapy (for Heat, Cold and Compression)	Available Heat: 10 minutes Cold: 10 minutes Total treatment: 5 cycles of alternating heat and cold treatment for total duration of 100 minutes	Available Heat: 10 minutes Cold: 10 minutes Total treatment: 5 cycles of alternating heat and cold treatment for total duration of 100 minutes	Available Heat: 1 – 10 minutes, default 3 minutes Cold: 1 – 10 minutes, default 3 minutes Total treatment: 15 – 90 minutes, default 30 minutes	Available Heat: 10 minutes Cold: 20 minutes	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149). Therm-X (K190854) Contrast therapy function is equivalent to the Med4 Elite™.

Characteristic	Therm-X (this submission - K190854)	Therm-X (K181149) Primary predicate	Med4 Elite™ (K171685) Secondary Predicate	VascuTherm™ (and NanoTherm™) (K061866) Secondary Predicate	Comparisons
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.	Not available	30 minutes (presumed not clearly stated in User Manual)	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149). Both Therm-X (K190854) and VascuTherm™ provide DVT. DVT Cycle Length for Therm-X (K190854) does not have a specified interval and provides clinicians the ability to prescribe DVT treatments for any length of minutes. At all times during treatment, the user has complete control and ability to stop the cycle and continue the cycle at any time.

Characteristic	Therm-X (this submission - K190854)	Therm-X (K181149) Primary predicate	Med4 Elite™ (K171685) Secondary Predicate	VascuTherm™ (and NanoTherm™) (K061866) Secondary Predicate	Comparisons
Edema Compression and DVT Compression at the same time	Available Edema Compression (Low, Medium, High) must be combined with cold, heat or contrast therapy.	Available Edema Compression (Low, Medium, High) must be combined with cold, heat or contrast therapy.	DVT not available	Available with or without cold, heat or contrast therapy	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149). The ability of Therm-X (K190854) to provide Edema and DVT compression treatment at the same time is identical to Vascutherm™. The only difference is that for Therm-X (K190854), the Edema compression must be combined with cold, heat or contrast therapy. This difference does not affect the intended use or the safety and effectiveness of the device.

Characteristic	Therm-X (this submission - K190854)	Therm-X (K181149) Primary predicate	Med4 Elite™ (K171685) Secondary Predicate	VascuTherm™ (and NanoTherm™) (K061866) Secondary Predicate	Comparisons
DVT Inflation and Deflation	DVT Inflation: Up to 60 seconds DVT Deflation: Up to 30 seconds	DVT Inflation: Up to 60 seconds DVT Deflation: Up to 30 seconds	Not available	Cycle time Inflation 20 seconds, Deflation 40 sec	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149). The DVT inflation and Deflation for Therm-X (K190854) is equivalent to VascuTherm™ with the difference that DVT inflation time is longer for Therm-X and DVT deflation is faster, which creates greater comfort and convenience for the user. This difference does not affect the intended use or the safety and effectiveness of the device.
Power Down	Available	Available	Snooze function Available	Not Available	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149).
Password Protection	Available for Therm-X AT and Therm-X Pro Models.	Available for Therm-X AT and Therm-X Pro Models.	Not Available	Not Available	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149).

Characteristic	Therm-X (this submission - K190854)	Therm-X (K181149) Primary predicate	Med4 Elite™ (K171685) Secondary Predicate	VascuTherm™ (and NanoTherm™) (K061866) Secondary Predicate	Comparisons
Store Cycle Usage Data	Available	Available	Not Available	Not Available	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149).
Physical Unit					
Dimensions	15” L x 10.5” W x 9” H	15” L x 10.5” W x 9” H	32.5” L x 24.75” W x 43” H (83 cm L x 63 cm W x 109cm H)	9.88” H x 8.75” D x 9.81” W (251 mm H x 222 mm D x 249 mm W)	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149).
Weight	15 lbs when full of coolant	15 lbs when full of coolant	172 lbs (78 kg)	10 lbs without fluid Weight Uknown when full of coolant	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149). Therm-X (K190854) is equivalent to VascuTherm™.
Chilling Mechanism	Thermoelectric	Thermoelectric	Vapor compression	Thermoelectric	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149). The chilling mechanism for Therm-X (K190854) is identical to the VascuTherm™.

Characteristic	Therm-X (this submission - K190854)	Therm-X (K181149) Primary predicate	Med4 Elite™ (K171685) Secondary Predicate	VascuTherm™ (and NanoTherm™) (K061866) Secondary Predicate	Comparisons
Heating Mechanism	Thermoelectric	Thermoelectric	Resistance heaters	Thermoelectric	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149). The heating mechanism for Therm-X (K190854) is identical to the VascuTherm™.
Reservoir Fluid Capacity	650 mL	650 mL	Heat reservoir: 1 gallon (3.8 L) Cold reservoir: 1 gallon (3.8 L)	8.5 fl oz (250 mL)	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149). The Therm-X (K190854) fluid capacity is smaller than the Med4 Elite since it is designed for only one patient at a time. The Therm-X (K190854) fluid capacity is larger than VascuTherm. The Therm-X fluid capacity is designed to address the longest cycle of treatment without having to refill the coolant.

Characteristic	Therm-X (this submission - K190854)	Therm-X (K181149) Primary predicate	Med4 Elite™ (K171685) Secondary Predicate	VascuTherm™ (and NanoTherm™) (K061866) Secondary Predicate	Comparisons
User Interface	Touch Screen	Touch Screen	Touch Screen	Touch Screen	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149), Med4 Elite™, and VascuTherm™.
Recommended Coolant	90% Distilled Water, 10% Isopropyl Alcohol	90% Distilled Water, 10% Isopropyl Alcohol	Distilled Water	90% Distilled Water, 10% Isopropyl Alcohol	The recommended coolant for Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149) and VascuTherm™. Each device is able to attain its desired performance requirements. There is no impact on the intended use or the safety and effectiveness of the device.
Electrical					
Line Voltage	100-240 VAC	100-240 VAC	100-240 VAC	100-240 VAC	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149), Med4 Elite™, and VascuTherm™.

Characteristic	Therm-X (this submission - K190854)	Therm-X (K181149) Primary predicate	Med4 Elite™ (K171685) Secondary Predicate	VascuTherm™ (and NanoTherm™) (K061866) Secondary Predicate	Comparisons
Line Frequency	50/60 Hz	50/60 Hz	50/60 Hz	50/60 Hz	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149), Med4 Elite™, and VascuTherm™.
Electrical Safety Standards	ANSI/AAMI ES60601-1:2005/(R)2012 Type BF Class II IEC 60601-1-2	ANSI/AAMI ES60601-1:2005/(R)2012 Type BF Class II IEC 60601-1-2	ANSI/AAMI ES60601-1:2005/(R)2012 CAN/CSA C22.2 No. 60601-1:2014 Type B	IEC 60601-1 UL 60601 Type B Class II IEC 60601-1-2	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149). Therm-X (K190854) is equivalent to Med4 Elite™. Therm-X (K190854) complies with the same electrical safety standards for the US markets.
Environment					
Operating Temperature	60°F – 80°F (16°C – 27°C)	60°F – 80°F (16°C – 27°C)	50°F – 90°F (10°C – 32°C)	60°F – 80°F (16°C – 27°C)	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149) and VascuTherm™. Therm-X (K190854) is equivalent to Med4 Elite™.

Characteristic	Therm-X (this submission - K190854)	Therm-X (K181149) Primary predicate	Med4 Elite™ (K171685) Secondary Predicate	VascuTherm™ (and NanoTherm™) (K061866) Secondary Predicate	Comparisons
Storage Temperature	33°F – 122°F (1°C to 50°C)	33°F – 122°F (1°C to 50°C)	33°F – 122°F (1°C to 50°C)	32°F – 122°F (0°C to 50°C)	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149). Therm-X (K190854) is equivalent to Med4 Elite ™ and VascuTherm™.
Operating Humidity	Below 60% Non-condensing	Below 60% Non-condensing	30 to 90% Non-condensing	Below 60% Non-condensing	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149) and VascuTherm™.
Storage Humidity	Below 60% Non-condensing	Below 60% Non-condensing	10 to 95% Non-condensing	10 to 95% Non-condensing	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149). Therm-X (K190854) is equivalent to the Med4 Elite™ and VascuTherm™. Therm-X (K190854) has a lower minimum and maximum limit for storage humidity. This difference does not affect the intended use or the safety and effectiveness of the device.

Characteristic	Therm-X (this submission - K190854)	Therm-X (K181149) Primary predicate	Med4 Elite™ (K171685) Secondary Predicate	VascuTherm™ (and NanoTherm™) (K061866) Secondary Predicate	Comparisons
Operating Atmospheric Pressure and Altitude	700 hPa – 1060 hPa (corresponds to a max. elevation of 9,842 ft 6 in (3000 m))	700 hPa – 1060 hPa (corresponds to a max. elevation of 9,842 ft 6 in (3000 m))	700 hPa – 1060 hPa (corresponds to a max. elevation of 9,842 ft 6 in (3000 m))	Unknown	The Therm-X (K190854) Operating atmospheric pressure and altitude is identical to the primary predicate, Therm-X (K181149) and Med4Elite™.
Accessories (Garments)					
Types of Garments	Various anatomical thermal garments for: Back, Elbow, Shoulder, Knee, Ankle, DVT Garments: Calf and Foot	Various anatomical thermal garments for: Back, Elbow, Shoulder, Knee, Ankle, 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	Various anatomical Wraps in different sizes for: Full leg, Knee segmental & ROM, Half Arm, Foot/Ankle, Shoulder w/ brace, Back w/ & w/o brace, lower & upper Cervical, Hip, Wrist-Hand, Arm, Half leg knee, Head, Face, DVT Garments: Calf and Foot	The Therm-X (K190854) garments are identical to the primary predicate, Therm-X (K181149), garments. Therm-X (K190854) thermal garments are identical to the thermal wraps for Med4 Elite™, however, Med4 Elite™ have more garments available. Therm-X (K190854) DVT garments are identical to VascuTherm™.

Characteristic	Therm-X (this submission - K190854)	Therm-X (K181149) Primary predicate	Med4 Elite™ (K171685) Secondary Predicate	VascuTherm™ (and NanoTherm™) (K061866) Secondary Predicate	Comparisons
Patient Contacting Material	Thermal garment – 30 denier nylon DVT garment – 200 denier nylon	Thermal garment – 30 denier nylon DVT garment – 200 denier nylon	70 Denier nylon Silcryn (hose covering)	Thermal wrap - 200 Denier Nylon Oxford DVT wrap – DuPont Softesse® Medical Fabric (non-latex, non-woven)	The patient contacting materials for the Therm-X (K190854) garments are identical to the primary predicate, Therm-X (K181149) The patient contacting material for the Therm-X (K190854) DVT garment is identical to the VascuTherm™ thermal wrap. The patient contacting material for the Therm-X (K190854) thermal garment is equivalent to Med4 Elite™ and VascuTherm thermal wrap.

Characteristic	Therm-X (this submission - K190854)	Therm-X (K181149) Primary predicate	Med4 Elite™ (K171685) Secondary Predicate	VascuTherm™ (and NanoTherm™) (K061866) Secondary Predicate	Comparisons
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	No information	The biocompatibility testing performed for Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149) and Med4 Elite™.
Sterile/Non-Sterile	Non-sterile only	Non-sterile only	Non-sterile only	Sterile and non-sterile	Therm-X (K190854) is identical to the primary predicate, Therm-X (K181149), Med4 Elite™, and VascuTherm™. The only difference is that VascuTherm provides sterile wraps in addition to non-sterile wraps. This difference does not affect the intended use or the safety and effectiveness of the device.
Reusable Wraps	Yes	No, single use wraps only	Yes	Yes	Therm-X (K190854) is identical to the VascuTherm™ and and Med4 Elite™.

Characteristic	Therm-X (this submission - K190854)	Therm-X (K181149) Primary predicate	Med4 Elite™ (K171685) Secondary Predicate	VascuTherm™ (and NanoTherm™) (K061866) Secondary Predicate	Comparisons
Cleaning Disinfection validation of labeling	Yes	N/A	Yes	Unknown	Therm-X (K190854) cleaning and disinfection validation of repeated cleaning and disinfection for reusable garments is equivalent to Med4 Elite™.
Human Factors Testing to confirm intended users have found instructions for cleaning and disinfection easy to use	Yes	N/A	Yes	Unknown	Therm-X (K190854) Human Factors validation of repeated cleaning and disinfection for reusable garments is equivalent to Med4 Elite™.
Expected Life of reusable garments	Based on frequency of use and continued functional performance	N/A	Based on frequency of use and continued functional performance	Unknown	Therm-X (K190854) garments are equivalent to Med4 Elite™ garments.
Validation of repeated cleaning and disinfection for reusable garments	Yes	N/A	Yes	Unknown	Therm-X (K190854) validation of repeated cleaning and disinfection for reusable garments is equivalent to Med4 Elite™.

Testing

Therm-X and Therm-X software (K190854) have been verified and validated under K181149 in accordance with documented Verification & Validation plans and protocols to ensure conformance with established performance criteria. See below for the type of tests performed:

- Electromagnetic Compatibility / Electrical Safety:
- Biocompatibility
- Software Validation
- Performance Bench Testing
- Clinical Testing
- Human Factors / Usability

Therm-X Garments and reprocessing instructions have been verified and validated in accordance with "Guidance for Industry and Food and Drug Administration Staff: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" (March 17, 2015) and documented Verification & Validation plans and protocols to ensure conformance with established performance criteria. See below for the types of tests performed:

Performance – Bench:

The cleaning and disinfection processes used to reprocess Therm-X (K190854) have been validated. A cleaning validation study was performed and confirmed that the cleaning process is adequate to remove soil and contaminants. Similarly, a low-level disinfection validation study was performed and confirmed that the disinfection process is adequate to destroy pathogenic or other kinds of microorganisms by chemical means.

A durability accelerated aging test was performed and confirmed the safe use and disinfection of a Therm-X garment for the duration of the garment's life without evidence of deterioration of the garment due to cleaning and/or disinfection.

Human Factors / Usability:

Human Factors Validation Testing was performed following the Guidance for Industry and Food and Drug Administration Staff "Applying Human Factors and Usability Engineering to Medical Devices" (February 3, 2016). The Human Factors Validation study demonstrated that the cleaning and disinfection processes and instructions within each Therm-X garment Instructions for Use (IFU) have been found to be safe and effective for the intended clinical users in the US market and for the intended uses and use environments of the Therm-X system (K190854). The study showed that the IFU for each Therm-X garment are able to be understood as it relates to the cleaning and disinfection processes and that users are able to adequately clean and disinfect the garments following the processes outlined in the IFUs.

Substantial Equivalence Conclusions

In conclusion, the indications for use of Therm-X (K190854) are identical to Therm-X (K181149). The technological characteristics and testing demonstrate that Therm-X is substantially equivalent to the predicate devices (Therm-X (K181149), Med4 Elite™ and VascuTherm™), assuring that Therm-X (K190854) is as safe and effective as the predicate devices.

Conclusion

The abbreviated 510(k) Pre-market Notification for Therm-X (K190854) contains adequate information and data to determine that Therm-X is as safe and effective as the legally marketed predicate devices.