August 3, 2018

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

Re: K181149
Trade/Device Name: Therm-X Pro, Therm-X Pro Athlete, Therm-X AT
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP, ILO, JOW
Dated: June 7, 2018
Received: June 7, 2018

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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K181149

Device Name
Therm-X Pro, Therm-X Pro Athlete, Therm-X AT

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.

510(k) Summary

Zenith Technical Innovations K181149

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

Submitter: Zenith Technical Innovations, LLC. (Zenith)
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Chief Technology Officer

Date Prepared: June 7, 2018

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	Reference
Trade Name:	Med4 Elite™	VascuTherm™ (and NanoTherm™)	GameReady® Classic System (GR 2)	IC-BAP-DL BioArterial Plus Aterial Blood Flow Enhancement System
Common Name:	Heat and/or Cold and Compression Therapy	Intermittent, External Pneumatic Compression Device	Cold/compression therapy system	BAP-DL BioArterial Plus Arterial Blood Flow Intermittent Circulator
510(k) Submitter / Holder:	CoolSystems, Inc.	ThermoTek, Inc.	CoolSystems, Inc.	Bio Compression Systems, Inc

510(k) Number:	K171685	K061866	K072620	K131327
Classification:	Class II	Class II	Class II	Class II
Regulation Number:	890.5650, Powered Inflatable tube massager	870.5800, Compressible limb sleeve	890.5650, Powered inflatable tube massager	870.5800, Compressible limb sleeve
Classification Panel:	Physical Medicine	Cardiovascular	Physical Medicine	Cardiovascular
Product Code:	IRP, ILO	JOW, ILO	IRP, ILO	JOW

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 single-patient use 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.

The 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 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 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

The Therm-X was assessed to determine the risks to health associated with the use of the device and evaluated 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 is substantially equivalent to Med4 Elite by Coolsystems, Inc. (K171685), VascuTherm by ThermoTek, Inc. (K061866), GameReady® Classic System (GR 2) by Coolsystems, Inc. (K072620), and IC-BAP-DL BioArterial Plus Aterial Blood Flow Enhancement System by Bio Compression Systems, Inc, (K131327) currently on the market.

Therm-X 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.

The table below provides a detailed comparison of Therm-X to the predicate devices.

Detailed Comparison of the Subject and Predicate Device

Characteristic	Therm-X (this submission)	Med4 Elite™ (K171685) Primary predicate	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) Secondary Predicate	Game Ready® Classic System (GR 2) (K072620) Secondary Predicate	Comparisons and Reference Device
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	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 rehabilitation facilities, outpatient clinics, and athletic training settings.	Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema. Reduction of edema associated with soft tissue injuries such as bums, postoperative edema, and ligament sprains.	It is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain for which cold and compression are indicated. It is intended to be used by or on the order of licensed healthcare professionals in hospitals, outpatient clinics, athletic training settings, or home settings.	The indications for use of the Therm-X 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) are also identical to VascuTherm™

Characteristic	Therm-X (this submission)	Med4 Elite™ (K171685) Primary predicate	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) Secondary Predicate	Game Ready® Classic System (GR 2) (K072620) Secondary Predicate	Comparisons and Reference Device
	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 healthcare professionals in rehabilitation facilities, outpatient clinics, athletic training settings, and home settings.		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. Treat and assist healing of cutaneous ulceration (wounds), reduce would healing time, enhance arterial circulation		for DVT therapy and for use in home settings. The indications for use of the Therm-X are equivalent to Game Ready® for use in home settings with the only difference being that Game Ready does not provide DVT Therapy.

Characteristic	Therm-X (this submission)	Med4 Elite™ (K171685) Primary predicate	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) Secondary Predicate	Game Ready® Classic System (GR 2) (K072620) Secondary Predicate	Comparisons and Reference Device
			(blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications.		
Intended Users	Healthcare Professionals and patients (i.e. General Patient Users and "Professional" Athlete Users at home under prescription)	Healthcare Professionals only (Prescription use)	Healthcare Professionals only and patients (at home under prescription)	Healthcare Professionals and patients (at home under prescription)	Therm-X intended users are identical to the intended users of the VascuTherm™ and Game Ready®.

Characteristic	Therm-X (this submission)	Med4 Elite™ (K171685) Primary predicate	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) Secondary Predicate	Game Ready® Classic System (GR 2) (K072620) Secondary Predicate	Comparisons and Reference Device
					Therm-X intended users are equivalent to the Med4 Elite™ with the only difference being that the intended users for the Med4 Elite™ do not include patients in the home setting.
Number of Patients that can be treated at one time	One	Two	One	One	Therm-X is designed to treat one patient at a time and it is identical to the VascuTherm™ and the Game Ready®.

Characteristic	Therm-X (this submission)	Med4 Elite™ (K171685) Primary predicate	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) Secondary Predicate	Game Ready® Classic System (GR 2) (K072620) Secondary Predicate	Comparisons and Reference Device
Two Programmable Cycles	Configuration of two programmable cycles are available for all Therm-X Models	Configuration of two programmable cycles (one cycle per patient)	Configuration of three programmable cycles (therapy profiles)	Not Available	The Therm-X is equivalent to the Med4 Elite™ and VascuTherm™.
Functions					
Heat Therapy Temperatures	Default: 105, 107, 110°F Custom: 105°F – 110°F	95 – 113°F (35 – 45°C)	105°F	Not available	The Therm-X Heat Therapy Temperature Range is equivalent to the Med4 Elite™.
Cold Therapy Temperatures	Default: 34, 45, 55°F Custom: 34 – 55°F	38 – 60°F (3.33 – 15.56°C)	43 – 49°F	34 – 50°F	The Therm-X temperature range for Cold Therapy is equivalent to the Med4 Elite™ and Game Ready®. The Therm-X minimum temperature range for Cold Therapy is

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					identical to Game Ready®. The Therm-X maximum temperature range for Cold Therapy is equivalent to Med4 Elite™.
Edema Compression combined with heat, cold or contrast therapy	Available	Available with or without heat therapy, cold therapy or contrast therapy.	Available with or without heat therapy, cold therapy or contrast therapy (contrast therapy is available only in VascuTherm™ 5).	Available with cold therapy.	Therm-X is identical to Game Ready® for combining edema compression with cold therapy. The Therm-X is equivalent to the Med4 Elite™ and VascuTherm™ with the difference that Med4 Elite™ and VascuTherm™

Characteristic	Therm-X (this submission)	Med4 Elite™ (K171685) Primary predicate	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) Secondary Predicate	Game Ready® Classic System (GR 2) (K072620) Secondary Predicate	Comparisons and Reference Device
					also provide compression without heat, cold or contrast therapy.
Edema Compression Levels	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)	Available in three levels Low (5 – 15 mm Hg) Medium (5 – 50 mm Hg) High (5 – 75 mm Hg)	The edema compression levels for Therm-X are equivalent to the compression levels for the Med4 Elite™ and Game Ready. Therm-X like VascuTherm™ provides constant values for Low, Medium and High compression.
DVT Only	Available for Therm-X Pro Athlete and Therm-X Pro Models.	Not Available	Available	Not Available	Therm-X Pro Athlete and Therm-X Pro

Characteristic	Therm-X (this submission)	Med4 Elite™ (K171685) Primary predicate	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) Secondary Predicate	Game Ready® Classic System (GR 2) (K072620) Secondary Predicate	Comparisons and Reference Device
					Models are identical to VascuTherm™.
DVT Compression	Calf: 50 - 70 mm Hg Foot: 100 – 130 mm Hg	Not available	Calf: 45 mm Hg Foot: 100 mm Hg	Not available	Therm-X (Therm-X Pro and Therm-X Pro Athlete Models) has a higher range for Foot and Calf DVT compression than the Vascutherm™ and has equivalent DVT compression to reference predicate, IC-BAP-DL BioArterial Plus Arterial Blood Flow Enhancement System (K131327)

Characteristic	Therm-X (this submission)	Med4 Elite™ (K171685) Primary predicate	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) Secondary Predicate	Game Ready® Classic System (GR 2) (K072620) Secondary Predicate	Comparisons and Reference Device
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: 5 to 30 minutes, 15 minutes default Cold: 5 to 60 minutes, 15 minutes default Compression Only: 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: Unknown	Heat: Not available Cold: 5 to 90 minutes, 15 minutes default Compression: Not available	The Therm-X Cycle length for Heat, Cold and Compression is equivalent to Med4 Elite™.
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: 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 Contrast therapy is available only in VascuTherm™ 5	Not available	Therm-X Contrast therapy function is equivalent to the Med4 Elite™.
DVT Cycle Length	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)	Not available	Both the Therm-X (Therm-X Pro and Therm-X Pro Athlete Models) and VascuTherm™ provide DVT.

Characteristic	Therm-X (this submission)	Med4 Elite™ (K171685) Primary predicate	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) Secondary Predicate	Game Ready® Classic System (GR 2) (K072620) Secondary Predicate	Comparisons and Reference Device
					DVT Cycle Length for Therm-X does not have a specified interval and provides healthcare professionals 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.
Edema Compression and DVT	Available .	DVT not available	Available	DVT not available	The ability of the Therm-X (Therm-X Pro

Characteristic	Therm-X (this submission)	Med4 Elite™ (K171685) Primary predicate	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) Secondary Predicate	Game Ready® Classic System (GR 2) (K072620) Secondary Predicate	Comparisons and Reference Device
Compression at the same time					and Therm-X Pro Athlete Models) to provide Edema and DVT compression treatment at the same time is identical to Vascutherm™.
DVT Inflation and Deflation	DVT Inflation: Up to 60 seconds DVT Deflation: Up to 30 seconds	Not available	Cycle time Inflation 20 seconds, Deflation 40 sec	Not available	The DVT inflation and Deflation for Therm-X (Therm-X Pro and Therm-X Pro Athlete Models) is equivalent to VascuTherm™ with the difference that DVT inflation time is longer for Therm-X and DVT deflation is

Characteristic	Therm-X (this submission)	Med4 Elite™ (K171685) Primary predicate	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) Secondary Predicate	Game Ready® Classic System (GR 2) (K072620) Secondary Predicate	Comparisons and Reference Device
					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.
Rest Timer	Available	Snooze function Available	Available	Sleep option available	Therm-X is identical to the VascuTherm™ and equivalent to the Med4 Elite™ and Game Ready®.
Pre-programmed cycles (Quick Picks)	Available	Available, Med4 Elite™ allows user to setup default settings for heat, cold, contrast and compression therapy.	Configuration of three programmable cycles (therapy profiles) in VascuTherm™ 5	Available	Therm-X is identical to Game Ready® and equivalent to Med4 Elite™ and

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					VascuTherm™ 5.
Password Protection (Modification of settings)	Available for Therm-X AT and Therm-X Pro Models.	Available, only users with password can adjust system default settings	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.	Not Available	The Therm-X is identical to the VascuTherm™ and equivalent to the Med4 Elite™.
Store Cycle Usage Data	Available	Available	Not Available	Not Available	The Therm-X is identical to the Med4 Elite™.
Physical Unit					
Dimensions	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)	VascuTherm™ 5 13.2” H x 12.00” D x 6.6” W (335 mm H x 305 mm D x 167 mm W)	16.25” L x 7.75” W x 9.25” H (413 x 197 x 235) mm (not including carrying case)	Therm-X is equivalent to Game Ready®. .

Characteristic	Therm-X (this submission)	Med4 Elite™ (K171685) Primary predicate	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) Secondary Predicate	Game Ready® Classic System (GR 2) (K072620) Secondary Predicate	Comparisons and Reference Device
			VascuTherm™ 4: 9.88" H x 8.75" D x 9.81" W (251 mm H x 222 mm D x 249 mm W)		
Weight	15 lbs when full of coolant	172 lbs (78 kg)	VascuTherm™ 5: 18.75 lbs (8.5 kg) VascuTherm™ 4: 9.5 lbs	7.3 lbs (3.31 kgs) empty Approximately 18 lbs full of ice and water	Therm-X is equivalent to VascuTherm™ 5 and Game Ready® .
Chilling Mechanism	Thermoelectric	Vapor compression	Thermoelectric	Ice	The chilling mechanism for the Therm-X is identical to the VascuTherm™.
Heating Mechanism	Thermoelectric	Resistance heaters	Thermoelectric	Not applicable	The heating mechanism for the Therm-X is identical to the VascuTherm™.
Reservoir Fluid Capacity	650 mL	Heat reservoir: 1 gallon (3.8 L) Cold reservoir: 1 gallon (3.8 L)	8.5 fl oz (250 mL)	Cold reservoir only for ice and water: 1.25 gallons	The Therm-X fluid capacity is smaller than the Med4 Elite ™ since it is designed for

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					only one patient at a time. The Therm-X 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. The fluid capacity does not affect the intended use, or
User Interface	Touch Screen	Touch Screen	Touch Screen	No	Therm-X is identical to the Med4 Elite™ and VascuTherm™.

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Recommended Coolant	90% Distilled Water, 10% Isopropyl Alcohol	Distilled Water	90% Distilled Water, 10% Isopropyl Alcohol	Tap Water and ice	The recommended coolant for the Therm-X is identical to the 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 is identical to Med4 Elite™, VascuTherm™ and Game Ready®.
Line Frequency	50/60 Hz	50/60 Hz	50/60 Hz	50/60 Hz	Therm-X is identical to Med4 Elite™,

Characteristic	Therm-X (this submission)	Med4 Elite™ (K171685) Primary predicate	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) Secondary Predicate	Game Ready® Classic System (GR 2) (K072620) Secondary Predicate	Comparisons and Reference Device
					VascuTherm™ and Game Ready®.
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 CAN/CSA C22.2 No. 60601-1:2014 Type B	IEC 60601-1 UL 60601 Type B Class II IEC 60601-1-2	ANSI/AAMI ES60601-1:2005/(R)2012 CAN/CSA C22.2 No. 60601-1:2014 Type BF Class I IEC 60601-1-2	Therm-X is equivalent to Med4 Elite™. Therm-X complies with the same electrical safety standards for the US markets.
Environment					
Operating Temperature	60°F – 80°F (16°C – 27°C)	50°F – 90°F (10°C – 32°C)	60°F – 80°F (16°C – 27°C)	33.8°F – 104°F(1-40°C)	Therm-X is identical to VascuTherm™. Therm-X is equivalent to Med4 Elite™ and Game Ready®.
Storage Temperature	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)	33°F – 122°F (1°C to 50°C)	Therm-X is equivalent to Med4 Elite ™, VascuTherm™

Characteristic	Therm-X (this submission)	Med4 Elite™ (K171685) Primary predicate	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) Secondary Predicate	Game Ready® Classic System (GR 2) (K072620) Secondary Predicate	Comparisons and Reference Device
					and Game Ready®.
Operating Humidity	Below 60% Non-condensing	30 to 90% Non-condensing	Below 60% Non-condensing	30 to 90% Non-condensing	Therm-X is identical to the VascuTherm™.
Storage Humidity	Below 60% Non-condensing	10 to 95% Non-condensing	10 to 95% Non-condensing	10 to 95% Non-condensing	Therm-X is equivalent to the Med4 Elite™, VascuTherm™ and Game Ready®. Therm-X has a lower minimum and maximum limit for storage humidity than the predicates. This difference does not affect the intended use or the safety and effectiveness of the device.
Operating Atmospheric	700 hPa – 1060 hPa (corresponds to a	700 hPa – 1060 hPa	Unknown	Atmospheric pressure at	The Therm-X Operating

Characteristic	Therm-X (this submission)	Med4 Elite™ (K171685) Primary predicate	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) Secondary Predicate	Game Ready® Classic System (GR 2) (K072620) Secondary Predicate	Comparisons and Reference Device
Pressure and Altitude	max. elevation of 9,842 ft 6 in (3000 m))	(corresponds to a max. elevation of 9,842 ft 6 in (3000 m))		0 – 8,000 Ft (0 – 2,500 m)	atmospheric pressure and altitude is identical to the Med4 Elite™.
Accessories (Garments)					
Types of Garments	Various anatomical thermal garments for: Back, Elbow, Shoulder, Knee, Ankle, DVT Garments: Calf and Foot	Various anatomical wraps in different sizes for: Straight Knee, Flexed Elbow, Ankle, Shoulder, Back,	Various anatomical Wraps in different sizes for: Back, Large Knee, Foot/Ankle Wrap (Open Heel), Foot/Ankle (Elbow Wrap), Standard Shoulder, DVT Garments: Calf and Foot	Various anatomical Wraps in different sizes for: Straight Knee, Straight Elbow, Ankle, Shoulder, Back,	Therm-X thermal garments are equivalent to the thermal wraps for Med4 Elite™, VascuTherm™ and Game Ready®, Therm-X DVT garments are equivalent to VascuTherm™.
Patient Contacting Material	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	70 Denier nylon	The patient contacting material for the Therm-X DVT garment is identical to the

Characteristic	Therm-X (this submission)	Med4 Elite™ (K171685) Primary predicate	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) Secondary Predicate	Game Ready® Classic System (GR 2) (K072620) Secondary Predicate	Comparisons and Reference Device
			Softesse® Medical Fabric (non-latex, non-woven)		VascuTherm™ thermal wrap. The patient contacting material for the Therm-X thermal garment is equivalent to Med4 Elite™, Game Ready® and VascuTherm thermal wrap.
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	Cytotoxicity testing per ISO 10993-5 Sensitization testing per ISO 10993-10 Irritation testing per ISO 10993-10	The biocompatibility testing performed for Therm-X is identical to the Med4 Elite™ and Game Ready®.
Sterile/Non-Sterile	Non-sterile only	Non-sterile only	Sterile and non-sterile	Non-sterile only	Therm-X is identical to Med4 Elite™, Game Ready®

Characteristic	Therm-X (this submission)	Med4 Elite™ (K171685) Primary predicate	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) Secondary Predicate	Game Ready® Classic System (GR 2) (K072620) Secondary Predicate	Comparisons and Reference Device
					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.
Single Patient Use	Yes	No	Yes, they provide both single patient and reusable wraps	No	Therm-X is identical to the VascuTherm™. The only difference is that VascuTherm™ also provides reusable wraps in addition to

Characteristic	Therm-X (this submission)	Med4 Elite™ (K171685) Primary predicate	VascuTherm™ (VascuTherm™ 4 and VascuTherm™ 5) and NanoTherm™) (K061866) Secondary Predicate	Game Ready® Classic System (GR 2) (K072620) Secondary Predicate	Comparisons and Reference Device
					the single patient use garments. This difference does not affect the intended use or the safety and effectiveness of the device.

Testing
Therm-X and Therm-X software were 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 test performed.

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.

Biocompatibility:
The Therm-X Unit is not patient contacting. The Therm-X garment patient contact 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.

Software Validation:
Zenith has conducted software validation testing on the Therm-X software and confirmed that Therm-X software met its performance requirements and specifications. Software Validation has been completed according to an established Validation procedure and FDA Guidance documents 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 Software Contained in Medical Devices, May 11, 2005

The Software is a Moderate Level of Concern as per FDA guidance. All required items related to software as required by FDA guidance have been included in this submission.

Performance – Bench:
The Therm-X was tested for performance to verify the proper operation of the system.

Test and verification results indicate that Therm-X conforms to its predetermined specifications. Therm-X has been found to be adequately safe and effective for the intended users, its intended uses and use environments.

Clinical Testing:
Zenith has performed skin temperature testing for:

- Maximum time limit at the highest temperature setting
- Maximum time limit at the lowest temperature setting
- Contrast therapy at the default time limit and temperature settings

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

Human Factors / Usability:
Human Factors / Usability assessments were performed in a simulated use environment to optimize the device design and support the safe use of Therm-X. The results demonstrated that users can operate Therm-X as safely and as effectively as the predicate devices.

Substantial Equivalence Conclusions
In conclusion, the intended use for Therm-X is substantially equivalent to that of the predicate devices. The technological characteristics comparison demonstrates that Therm-X is equivalent to predicate devices, and the testing shows that Therm-X is substantially equivalent to the predicate devices and assures that Therm-X is as safe and effective as the predicate devices.

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