February 28, 2020

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

Re: K193550
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: December 19, 2019
Received: December 20, 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely,

For Vivek Pinto, Ph.D.
Director
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)*

K193550

Device Name

Therm-X

Indications for Use *(Describe)*

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.

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 K193550

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

Date Prepared: December 19, 2019

Device Name and Classification

Trade Name: Therm-X
Common Name: Massager, Powered Inflatable Tube
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	Reference
Trade Name:	Therm-X	Therm-X	Game Ready GRPro 2.1 System
Common Name:	Heat and/or Cold and Compression Therapy	Heat and/or Cold and Compression Therapy	Powered Inflatable Tube Massager
510(k) Submitter / Holder:	Zenith Technical Innovations, LLC. (Zenith)	Zenith Technical Innovations, LLC. (Zenith)	Cool Systems, Inc. (dba Game Ready)
510(k) Number:	K190854	K181149	K192114
Classification:	Class II	Class II	Class II
Regulation Number:	890.5650, Powered Inflatable tube massager	890.5650, Powered Inflatable tube massager	890.5650, Powered Inflatable tube massager
Classification Panel:	Physical Medicine	Physical Medicine	Physical Medicine
Product Code:	IRP, ILO, JOW	IRP, ILO, JOW	IRP, 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 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 consists of various reusable inflatable wraps for thermal treatment of the back, elbow, shoulder, ankle, hip, 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 shoulder, 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 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 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 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 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.

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

The Therm-X was assessed to determine the risks to health associated with the device modifications 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. All risks have been found acceptable.

Substantial Equivalence

Therm-X is substantially equivalent to Therm-X (K181149, K190854) by Zenith Technical Innovations, LLC. (Zenith) and Game Ready GRPro 2.1 System (K192114) by Cool Systems, Inc. (dba Game Ready) 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 ***Subject Device***	Therm-X (K190854) ***Primary Predicate***	Therm-X (K181149) ***Secondary Predicate***	GameReady® GRPro 2.1 System (K192114) ***Reference Device***	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 Home systems also provide DVT therapy. Therm-X Home systems with DVT therapy are	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-	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-	Game Ready® GRPro 2.1 System is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain where 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 (subject device) are identical to the Therm-X (K190854), with the only difference being that 1 model name has changed, and 1 model has been discontinued.

Characteristic	Therm-X *Subject Device*	Therm-X (K190854) *Primary Predicate*	Therm-X (K181149) *Secondary Predicate*	GameReady® GRPro 2.1 System (K192114) *Reference Device*	Comparison
	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.	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.	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.		

Characteristic	Therm-X ***Subject Device***	Therm-X (K190854) ***Primary Predicate***	Therm-X (K181149) ***Secondary Predicate***	GameReady® GRPro 2.1 System (K192114) ***Reference Device***	Comparison
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)	Healthcare professionals, athletic trainers, lay users under the direction of a healthcare professional	Therm-X (subject device) is identical to Therm-X (K190854).
Number of Patients that can be treated at one time	One	One	One	One	Therm-X (subject device) is identical to Therm-X (K190854).
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	Configuration of two programmable cycles are available for all Therm-X Models	Not publicly available.	Therm-X (subject device) is identical to Therm-X (K190854).
Functions					
Continuous Treatment Cycle	Available on Therm-X Home	Not Available	Not Available	Not publicly available	Therm-X (subject device) is equivalent to GameReady® GRPro 2.1 System (K192114).

Characteristic	Therm-X ***Subject Device***	Therm-X (K190854) ***Primary Predicate***	Therm-X (K181149) ***Secondary Predicate***	GameReady® GRPro 2.1 System (K192114) ***Reference Device***	Comparison
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: 105°F, 107°F, 110°F Custom: 105°F – 110°F	N/A	Therm-X (subject device) is equivalent to Therm-X (K190854). The only difference is that the heat therapy temperatures are more limited for continuous treatment, but fall within the range of what has been previously cleared.

Characteristic	Therm-X ***Subject Device***	Therm-X (K190854) ***Primary Predicate***	Therm-X (K181149) ***Secondary Predicate***	GameReady® GRPro 2.1 System (K192114) ***Reference Device***	Comparison
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: 34°F, 45°F, 55°F Custom: 34°F – 55°F	34 – 50°F	Therm-X (subject device) is equivalent to Therm-X (K190854). The only difference is that the cold therapy temperatures are more limited for continuous treatment, but fall within the range of what has been previously cleared.

Characteristic	Therm-X *Subject Device*	Therm-X (K190854) *Primary Predicate*	Therm-X (K181149) *Secondary Predicate*	GameReady® GRPro 2.1 System (K192114) *Reference Device*	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: 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 three levels: Low (20 mm Hg) Medium (45 mm Hg) High (70 mm Hg)	Available in three levels: Low (5-15 mm Hg) Medium (5-50 mm Hg) High (5-75 mm Hg)	Therm-X (subject device) is equivalent to Therm-X (K190854). The only difference is that the pressure levels are more limited for continuous treatment and an additional compression level (lite) has been included.
Static or Intermittent Pressure	Both	Static Pressure Only	Static Pressure Only	Intermittent Pressure available	Therm-X (subject device) is equivalent to Therm-X (K190854) and GameReady® GRPro 2.1 System (K192114).
DVT Only	Available for Therm-X Home Model	Available for Therm-X Pro Athlete and Therm-X Pro Models	Available for Therm-X Pro Athlete and Therm-X Pro Models	N/A	Therm-X (subject device) is equivalent to Therm-X (K190854).

Characteristic	Therm-X ***Subject Device***	Therm-X (K190854) ***Primary Predicate***	Therm-X (K181149) ***Secondary Predicate***	GameReady® GRPro 2.1 System (K192114) ***Reference Device***	Comparison
DVT Pressure	Calf: 50 – 70 mmHg Foot: 90 – 130 mmHg	Calf: 50 – 70 mmHg Foot: 100 – 130 mmHg	Calf: 50 – 70 mmHg Foot: 100 – 130 mmHg	N/A	Therm-X (subject device) is equivalent to Therm-X (K190854).
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	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	15 minutes default, increasing or decreasing in 5-minute increments to a max of 90 min or a min of 5 min.	Therm-X (subject device) is equivalent to Therm-X (K190854). The only difference is that a custom and continuous cycle length is available for the Therm-X Home model. Verification and validation testing has been performed to test the continuous treatment cycle. Note: K192114 does not offer heat therapy.

Characteristic	**Therm-X** ***Subject Device***	**Therm-X (K190854)** ***Primary Predicate***	**Therm-X (K181149)** ***Secondary Predicate***	**GameReady® GRPro 2.1 System (K192114)** ***Reference Device***	**Comparison**
Contrast Therapy	Available for Therm-X AT Model only Heat: 105°F Cold: 38°F	Available for all Therm-X Models Heat: 105°F Cold: 38°F	Available for all Therm-X Models Heat: 105°F Cold: 38°F	N/A	Therm-X (subject device) is equivalent to Therm-X (K190854). The only difference is that the contrast therapy is only available for Therm-X AT Model and not for Therm-X Home Model.
Cycle Length (for Contrast Therapy)	Heat: 3-10 minutes Cold: 3-10 minutes Total treatment: 6-60 minutes	Heat: 10 minutes Cold: 10 minutes Total treatment: 5 cycles of alternating heat and cold treatment for total duration of 100 minutes	Heat: 10 minutes Cold: 10 minutes Total treatment: 5 cycles of alternating heat and cold treatment for total duration of 100 minutes	N/A	Therm-X (subject device) is equivalent to Therm-X (K190854).
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.	No specified time interval. DVT can be stopped at any time by the user.	N/A	Therm-X (subject device) is identical to Therm-X (K190854).

Characteristic	Therm-X ***Subject Device***	Therm-X (K190854) ***Primary Predicate***	Therm-X (K181149) ***Secondary Predicate***	GameReady® GRPro 2.1 System (K192114) ***Reference Device***	Comparison
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 (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	N/A	Therm-X (subject device) is equivalent to Therm-X (K190854). Note: K192114 does not provide DVT.
DVT Inflation and Deflation	DVT Inflation: Up to 120 seconds DVT Deflation: Up to 30 seconds	DVT Inflation: Up to 60 seconds DVT Deflation: Up to 30 seconds	DVT Inflation: Up to 60 seconds DVT Deflation: Up to 30 seconds	N/A	Therm-X (subject device) is equivalent to Therm-X (K190854).
Power Down	Available	Available	Available	Sleep option	Therm-X (subject device) is identical to Therm-X (K190854).
Password Protection	Available	Available for Therm-X AT and Therm-X Pro Models.	Available for Therm-X AT and Therm-X Pro Models.	Not publicly available	Therm-X (subject device) is identical to Therm-X (K190854).
Store Cycle Usage Data	Available	Available	Available	Not publicly available	Therm-X (subject device) is identical to Therm-X (K190854).
Physical Unit					
Dimensions	15” L x 10.5” W x 9” H	15” L x 10.5” W x 9” H	15” L x 10.5” W x 9” H	16.25” L x 7.75” W x 9.25 H (413 x 197 x 235) mm (not including carrying case)	Therm-X (subject device) is identical to Therm-X (K190854).

Characteristic	Therm-X *Subject Device*	Therm-X (K190854) *Primary Predicate*	Therm-X (K181149) *Secondary Predicate*	GameReady® GRPro 2.1 System (K192114) *Reference Device*	Comparison
Weight	15 lbs. when full of coolant	15 lbs. when full of coolant	15 lbs. when full of coolant	7.3 lbs. (3.31 kg.) empty, Approximately 18 lbs. full of ice and water but less when filled per instructions for use	Therm-X (subject device) is identical to Therm-X (K190854).
Chilling Mechanism	Thermoelectric	Thermoelectric	Thermoelectric	Ice	Therm-X (subject device) is identical to Therm-X (K190854).
Heating Mechanism	Thermoelectric	Thermoelectric	Thermoelectric	Not applicable.	Therm-X (subject device) is identical to Therm-X (K190854).
Reservoir Fluid Capacity	650 mL	650 mL	650 mL	Approximately 5100 mL	Therm-X (subject device) is identical to Therm-X (K190854).
User Interface	Touch Screen	Touch Screen	Touch Screen	LCD Display and 9 buttons	Therm-X (subject device) is identical to Therm-X (K190854).
Recommended Coolant	90% Distilled Water, 10% Isopropyl Alcohol	90% Distilled Water, 10% Isopropyl Alcohol	90% Distilled Water, 10% Isopropyl Alcohol	Tap Water and Ice	Therm-X (subject device) is identical to Therm-X (K190854).

Characteristic	Therm-X *Subject Device*	Therm-X (K190854) *Primary Predicate*	Therm-X (K181149) *Secondary Predicate*	GameReady® GRPro 2.1 System (K192114) *Reference Device*	Comparison
Electrical					
Line Voltage	100-240 VAC	100-240 VAC	100-240 VAC	100-240 VAC	Therm-X (subject device) is identical to Therm-X (K190854).
Line Frequency	50/60 Hz	50/60 Hz	50/60 Hz	50/60 Hz	Therm-X (subject device) is identical to Therm-X (K190854).
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	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 & A1:2012, C1:2009 (R) 2012, A2:2010/(R) 2012- Part 1 CAN/CSA – C22.2 No. 60601- 1:14 Part 1 IEC 60601-1-6:2010 + A1:2013 IEC 60601-1-11:2015 IEC 60601 – 1-2, Ed. 4.0: 2014 BS EN 60601-1-2:2015 IEC 62366:2007 + A1:2014 IEC 62133:2012 + C1:2013	Therm-X (subject device) is identical to Therm-X (K190854).

Characteristic	Therm-X *Subject Device*	Therm-X (K190854) *Primary Predicate*	Therm-X (K181149) *Secondary Predicate*	GameReady® GRPro 2.1 System (K192114) *Reference Device*	Comparison
Environment					
Operating Temperature	60°F – 80°F (16°C – 27°C)	60°F – 80°F (16°C – 27°C)	60°F – 80°F (16°C – 27°C)	33.8°F – 104°F (1°C -40°C)	Therm-X (subject device) is identical to Therm-X (K190854).
Storage Temperature	33°F – 122°F (1°C - 50°C)	33°F – 122°F (1°C - 50°C)	33°F – 122°F (1°C - 50°C)	33°F -122°F (1°C – 50°C)	Therm-X (subject device) is identical to Therm-X (K190854).
Operating Humidity	Below 60% Non-condensing	Below 60% Non-condensing	Below 60% Non-condensing	Not publicly available	Therm-X (subject device) is identical to Therm-X (K190854).
Storage Humidity	Below 60% Non-condensing	Below 60% Non-condensing	Below 60% Non-condensing	15% - 90% non-condensing	Therm-X (subject device) is identical to Therm-X (K190854).
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))	0 - 9,843 ft. (0 - 3000 m)	Therm-X (subject device) is identical to Therm-X (K190854).

Characteristic	Therm-X *Subject Device*	Therm-X (K190854) *Primary Predicate*	Therm-X (K181149) *Secondary Predicate*	GameReady® GRPro 2.1 System (K192114) *Reference Device*	Comparison
Accessories (Garments)					
Types of Garments	Various anatomical thermal garments for: Back, Elbow, Shoulder, Knee, Ankle, Hip. DVT Garments: Calf and Foot	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, Straight Elbow, Ankle, Shoulder, Back, Traumatic Amputee, Neck, Lower Limb, Full Leg Boot and Chest	Therm-X (subject device) is equivalent to Therm-X (K190854). The only difference is that one additional type of garment for the hip is available. This new anatomical garment type is substantially equivalent to another reference device, Med4 Elite™ (K171685), for cold, heat, and contrast therapy of the hip.

Characteristic	Therm-X ***Subject Device***	Therm-X (K190854) ***Primary Predicate***	Therm-X (K181149) ***Secondary Predicate***	GameReady® GRPro 2.1 System (K192114) ***Reference Device***	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	Thermal garment (multi-patient) – 30 denier nylon coated in urethane DVT – 200 denier nylon coated in urethane	Thermal garment (multi-patient) – 30 denier nylon coated in urethane DVT – 200 denier nylon coated in urethane	70 denier nylon & polyester	Therm-X (subject device) is identical to Therm-X (K190854).
Multi-Patient Use or Single-Patient Use Wraps	Multi-Patient Use and Single-Patient Use Available	Multi-Patient Use	Multi-Patient Use	Not publicly available	Therm-X (subject device) is equivalent to Therm-X (K190854). The only difference is that Therm-X (subject device) now has both multi-patient and single-patient use garments available.

Characteristic	Therm-X ***Subject Device***	Therm-X (K190854) ***Primary Predicate***	Therm-X (K181149) ***Secondary Predicate***	GameReady® GRPro 2.1 System (K192114) ***Reference Device***	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	Cytotoxicity testing per ISO 10993-5 Sensitization testing per ISO 10993-10 Irritation testing per ISO 10993-10	Primary patient contacting components verified as acceptable according to ISO 10993-1 using cytotoxicity, primary irritation and skin sensitization. Additional elastomeric materials were verified as acceptable according to ISO 10993-1 using acute systematic toxicity, primary irritation and skin sensitization.	Therm-X (subject device) is identical to Therm-X (K190854).
Sterile/Non-Sterile	Non-sterile only	Non-sterile only	Non-sterile only	Non-sterile only	Therm-X (subject device) is identical to Therm-X (K190854).
Cleaning Disinfection Validation of Labeling	Yes – for Multi-Patient use reusable wraps	Yes – for Multi-Patient use reusable wraps	N/A	Yes	Therm-X (subject device) is identical to Therm-X (K190854).

Characteristic	Therm-X *Subject Device*	Therm-X (K190854) *Primary Predicate*	Therm-X (K181149) *Secondary Predicate*	GameReady® GRPro 2.1 System (K192114) *Reference Device*	Comparison
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	N/A	Not publicly available	Therm-X (subject device) is identical to Therm-X (K190854).
Expected Life of garments	Based on frequency of use and continued functional performance	Based on frequency of use and continued functional performance	N/A	Based on frequency of use	Therm-X (subject device) is identical to Therm-X (K190854).
Validation of repeated cleaning and disinfection for reusable garments	Yes – for Multi-Patient use reusable wraps	Yes – for Multi-Patient use reusable wraps	N/A	Yes	Therm-X (subject device) is identical to Therm-X (K190854).

In this submission, Zenith has added a new Therm-X garment anatomical type – hip. This new anatomical garment type is substantially equivalent to another reference device, Med4 Elite™ (K171685), for cold, heat, and contrast therapy of the hip.

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 tests 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 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.

Cleaning, Disinfection & Shelf Life Testing

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

Clinical Testing:
IRB approved studies have been performed to measure the lowest skin temperature the Therm-X device can generate. As required by the FDA guidance for heating and cooling devices, Therm-X 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 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 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 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 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 the 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.