July 27, 2023

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

Re: K231912
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: June 28, 2023
Received: June 29, 2023

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,

Tushar Bansal -S

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231912

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 K231912

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

Submitter: Zenith Technical Innovations, LLC. (Zenith)
1396 St. Paul Ave.
Gurnee, IL 60031
Phone: (847) 672-7481
Fax: (847) 672-8721

Primary Contact: Rita King, CEO
MethodSense, Inc.
Email: ritaking@methodsense.com
Phone: 919-313-3961

Company Contact: Greg Binversie
Chief Technical Officer

Date Prepared: June 28, 2023

Device Name and Classification

Trade Name: Therm-X
Common Name: Massage, 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 Device

Trade Name:	Therm-X
Common Name:	Heat and/or Cold and Compression Therapy
510(k) Submitter / Holder:	Zenith Technical Innovations, LLC. (Zenith)
510(k) Number:	K193550
Classification:	Class II
Regulation Number:	890.5650, Powered Inflatable tube massager
Classification Panel:	Physical Medicine
Product Code:	IRP, ILO, JOW

The predicate device has not been subject to a design-related recall.

Device Description

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

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

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

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

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 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 14971:2019, Medical devices -- Application of risk management to medical devices. No additional risks were associated with the release of the four new thermal garments for this submission.

Substantial Equivalence
Therm-X is substantially equivalent to Therm-X (K193550) by Zenith Technical Innovations, LLC. (Zenith).

Therm-X has the same intended use and indications for use as the predicate device and uses equivalent overall design and operating principals as the predicate device.

The table below provides a detailed comparison of Therm-X to the predicate device:

Detailed Comparison of the Subject and Predicate Device

Characteristic	**Therm-X** ***Subject Device***	**Therm-X (K193550)** ***Primary Predicate***	**Comparison**
Indications for Use	Therm-X (Therm-X Home and Therm-X AT) combines cold, heat, contrast, and compression therapy. Therm-X is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain for which cold and compression are indicated. It is intended to treat post traumatic and post-surgical medical and/or surgical conditions for which localized thermal therapy (hot or cold) are indicated. Therm-X 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.	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.	The indications for use of the Therm-X (subject device) are identical to the Therm-X (K193550).

Characteristic	Therm-X ***Subject Device***	Therm-X (K193550) ***Primary Predicate***	Comparison
Intended Users	Health Care Professionals and lay users (under prescription)	Health Care Professionals and lay users (under prescription)	Therm-X (subject device) is identical to Therm-X (K193550).
Number of Patients that can be treated at one time	Two	One	Therm-X (subject device) is different from Therm-X (K193550). This difference is limited to the ability of the Therm-X (subject device) to treat two patients instead of one via a split umbilical hose accessory. Verification and Validation testing have been conducted to confirm this difference does not affect the intended use or raise different questions of safety and effectiveness.
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	Therm-X (subject device) is identical to Therm-X (K193550).
Continuous Treatment Cycle	Available on Therm-X Home	Available on Therm-X Home	Therm-X (subject device) is identical to Therm-X (K193550).
Heat Therapy	Default: 105°F, 107°F, 110°F Custom: 105°F – 110°F Default, continuous: 105°F, 107°F Custom, continuous: 105°F – 107°F	Default: 105°F, 107°F, 110°F Custom: 105°F – 110°F Default, continuous: 105°F, 107°F Custom, continuous: 105°F – 107°F	Therm-X (subject device) is identical to Therm-X (K193550).

Characteristic	Therm-X ***Subject Device***	Therm-X (K193550) ***Primary Predicate***	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, continuous: 40°F, 45°F, 50°F Custom, continuous: 40°F – 50°F	Therm-X (subject device) is identical to Therm-X (K193550).
Edema Pressure Levels	Available in four levels: Lite (5 mm Hg) Low (20 mm Hg) Medium (45 mm Hg) High (70 mm Hg) For continuous treatment, available in three levels: Lite (5 mm Hg) Low (20 mm Hg) Medium (45 mm Hg)	Available in four levels: Lite (5 mm Hg) Low (20 mm Hg) Medium (45 mm Hg) High (70 mm Hg) For continuous treatment, available in three levels: Low (20 mm Hg) Medium (45 mm Hg) High (70 mm Hg)	Therm-X (subject device) is different to Therm-X (K193550). The difference is limited to the Therm-X (subject device) not providing the option for High pressure during Continuous treatment and allowing for Lite treatment during continuous treatment. This difference in options of compression levels for continuous treatments does not affect the intended use or raise different questions of safety and effectiveness.
Static or Intermittent Pressure	Both	Both	Therm-X (subject device) is identical to Therm-X (K193550).
DVT Only	Available for Therm-X Home Model	Available for Therm-X Home Model	Therm-X (subject device) is identical to Therm-X (K193550).

Characteristic	Therm-X ***Subject Device***	Therm-X (K193550) ***Primary Predicate***	Comparison
DVT Pressure	Calf: 50 – 70 mmHg Foot: 90 – 130 mmHg	Calf: 50 – 70 mmHg Foot: 90 – 130 mmHg	Therm-X (subject device) is identical to Therm-X (K193550).
Cycle Length (for Heat, Cold, and Compression)	Default: 10 or 20 minutes Custom: 3 – 40 minutes Continuous: 10 – 40 minutes active, 30-60 minutes rest	Default: 10 or 20 minutes Custom: 3 – 40 minutes Continuous: 10 – 40 minutes active, 30-60 minutes rest	Therm-X (subject device) is identical to Therm-X (K193550).
Contrast Therapy	Available for Therm-X AT Model only Heat: 105°F Cold: 38°F	Available for Therm-X AT Model only Heat: 105°F Cold: 38°F	Therm-X (subject device) is identical to Therm-X (K193550).
Cycle Length (for Contrast Therapy)	Heat: 3-10 minutes Cold: 3-10 minutes Total treatment: 6-60 minutes	Heat: 3-10 minutes Cold: 3-10 minutes Total treatment: 6-60 minutes	Therm-X (subject device) is identical to Therm-X (K193550).
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.	Therm-X (subject device) is identical to Therm-X (K193550).
Edema Compression and DVT Compression at the same time	Available Edema Compression (Lite, Low, Medium, High) must be combined with cold, heat, or contrast therapy	Available Edema Compression (Lite, Low, Medium, High) must be combined with cold, heat, or contrast therapy	Therm-X (subject device) is identical to Therm-X (K193550).
DVT Inflation and Deflation	DVT Inflation: Up to 120 seconds DVT Deflation: Up to 30 seconds	DVT Inflation: Up to 120 seconds DVT Deflation: Up to 30 seconds	Therm-X (subject device) is identical to Therm-X (K193550).

Characteristic	Therm-X ***Subject Device***	Therm-X (K193550) ***Primary Predicate***	Comparison
Power Down	Available	Available	Therm-X (subject device) is identical to Therm-X (K193550).
Password Protection	Available	Available	Therm-X (subject device) is identical to Therm-X (K193550).
Store Cycle Usage Data	Available	Available	Therm-X (subject device) is identical to Therm-X (K193550).
Dimensions	15” L x 10.5” W x 9” H	15” L x 10.5” W x 9” H	Therm-X (subject device) is identical to Therm-X (K193550).
Weight	15 lbs. when full of coolant	15 lbs. when full of coolant	Therm-X (subject device) is identical to Therm-X (K193550).
Chilling Mechanism	Thermoelectric	Thermoelectric	Therm-X (subject device) is identical to Therm-X (K193550).
Heating Mechanism	Thermoelectric	Thermoelectric	Therm-X (subject device) is identical to Therm-X (K193550).
Reservoir Fluid Capacity	650 mL	650 mL	Therm-X (subject device) is identical to Therm-X (K193550).
User Interface	Touch Screen	Touch Screen	Therm-X (subject device) is identical to Therm-X (K193550).

Characteristic	Therm-X ***Subject Device***	Therm-X (K193550) ***Primary Predicate***	Comparison
Recommended Coolant	90% Distilled Water, 10% Isopropyl Alcohol	90% Distilled Water, 10% Isopropyl Alcohol	Therm-X (subject device) is identical to Therm-X (K193550).
Line Voltage	100-240 VAC	100-240 VAC	Therm-X (subject device) is identical to Therm-X (K193550).
Line Frequency	50/60 Hz	50/60 Hz	Therm-X (subject device) is identical to Therm-X (K193550).
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	Therm-X (subject device) is identical to Therm-X (K193550).
Operating Temperature	40°F – 130°F (4.4°C – 54.4°C)	60°F – 80°F (16°C – 27°C)	Therm-X (subject device) is different than Therm-X (K193550). The difference is limited to the Therm-X (subject device) allowing for use of the device in a wider range of operating temperatures. This difference does not affect the intended use or raise different questions of safety and effectiveness.
Storage Temperature	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 (K193550).

Characteristic	Therm-X ***Subject Device***	Therm-X (K193550) ***Primary Predicate***	Comparison
Operating Humidity	Below 60% Non-condensing	Below 60% Non-condensing	Therm-X (subject device) is identical to Therm-X (K193550).
Storage Humidity	Below 60% Non-condensing	Below 60% Non-condensing	Therm-X (subject device) is identical to Therm-X (K193550).
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))	Therm-X (subject device) is identical to Therm-X (K193550).
Types of Garments	Various anatomical thermal garments for: Back, Elbow, Hand, Shoulder, XL Shoulder, Knee, Half-Leg, Ankle, Hip, Neck. DVT Garments: Calf and Foot	Various anatomical thermal garments for: Back, Elbow, Shoulder, Knee, Ankle, Hip. DVT Garments: Calf and Foot	Therm-X (subject device) is different to Therm-X (K193550). The difference is limited to the addition of four garments for new anatomical locations, and one XL version of an existing garment. This difference does not affect the intended use or raise different questions of safety or effectiveness.
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, 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	Therm-X (subject device) is identical to Therm-X (K193550).

Characteristic	Therm-X ***Subject Device***	Therm-X (K193550) ***Primary Predicate***	Comparison
Multi-Patient Use or Single-Patient Use Wraps	Multi-Patient Use and Single-Patient Use Available	Multi-Patient Use and Single-Patient Use Available	Therm-X (subject device) is identical to Therm-X (K193550).
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	Therm-X (subject device) is identical to Therm-X (K193550).
Sterile/Non-Sterile	Non-sterile only	Non-sterile only	Therm-X (subject device) is identical to Therm-X (K193550).
Cleaning Disinfection Validation of Labeling	Yes – for Multi-patient use reusable wraps	Yes – for Multi-patient use reusable wraps	Therm-X (subject device) is identical to Therm-X (K193550).
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	Therm-X (subject device) is identical to Therm-X (K193550).
Expected Life of garments	Based on frequency of use and continued functional performance	Based on frequency of use and continued functional performance	Therm-X (subject device) is identical to Therm-X (K193550).
Validation of repeated cleaning and disinfection for reusable garments	Yes – for Multi-patient use reusable wraps	Yes – for Multi-patient use reusable wraps	Therm-X (subject device) is identical to Therm-X (K193550).

In this submission, Zenith has added 4 new anatomical garment types: Multi-Patient Use Half Leg, Multi-Patient Use Hand, Single Patient Use (SPU) Hand, and SPU Cervical garments. Therm-X with these additional garments is substantially equivalent to the identified predicate (K193550).

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.

Performance – Bench

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

Electromagnetic Compatibility / Electrical Safety:

Electromagnetic Compatibility / Electrical Safety testing was performed in accordance with the following standards:

- IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests Verification results indicated that the device is safe
- IEC 60601-1-11: Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Biocompatibility:

The Therm-X 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
- Guidance for the Content of Premarket Submissions for Device Software Functions, June 14, 2023

The Therm-X software is a Moderate Level of Concern per FDA guidance Content of Premarket Submissions for Software Contained in Medical Devices from 2005: however, a new Guidance for the Content of Premarket Submissions for Device Software Functions from 2023 has since been released which changes the classifications of software. Per the new guidance, the Therm-X Software is classified as an Enhanced Document Level. As the Therm-X Software has a Declaration of Conformity with IEC 62304, no additional software documentation is required for the Enhanced Document Level classification.

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 indications for use of the Therm-X are identical to Therm-X (K193550). The technological characteristics and testing demonstrate that the Therm-X is substantially equivalent to the predicate device Therm-X (K193550), assuring that Therm-X is as safe and effective as the predicate device.

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 device.