July 8, 2026

Stihler Electronic GmbH
Gary Brennan
Regulatory Manager
Gaussstrasse 4
Leinfelden-Echterdingen, 70771
Germany

Re: K260278
Trade/Device Name: ThermAffyx(TM) Patient Safety System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ, LWG
Dated: June 3, 2026
Received: June 3, 2026

Dear Gary Brennan:

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

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

KATHLEEN M. GRUNDER -S

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

Enclosure

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)*
K260278

Device Name
ThermAffyx(TM) Patient Safety System

Indications for Use *(Describe)*
The ThermAffyx(TM) Patient Safety System is intended to maintain normothermia, treat hypothermia and provide anti-slip positioning securement for patients.
The system is intended to be used by trained healthcare professionals in all areas of professional healthcare facilities.

It is indicated for use on adult patients.

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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K260278

510(k) Summary

1. Submitter

Applicant Information: Stihler Electronic GmbH
Establishment Number: 9617473
Contact: Gary Brennan
Title: Regulatory Manager
Phone: 315-877-7298
Email: Gary.Brennan@Gentherm.com
Date Prepared: January 23, 2026

2. MANUFACTURER

Name: Stihler Electronic GmbH
Address Gaussstrasse 4,
70771 Leinfelden-Echterdingen, Germany

3. Device

Device Trade Name: ThermAffyx™ Patient Safety System
Classification Code : 21 CFR 870.5900
Classification Name: Thermal Regulating System
Regulatory Class: II
Product Code: DWJ; Associate Product Code LWG

4. Predicate Device(s)

Legally Marketed Predicate Device

510(k) Number	Product Code	Trade Name	Applicant
K202197	DWJ	ASTOPAD®	Stihler Electronics GmbH (part of Gentherm Medical, LLC)
NA Class 1 Exempt Device	LWG	PrimePad®	Prime Medical

5. Device Description

Stihler Electronics GmbH is developing a Patient Warming System and single use disposable pad that can be used underneath patients during procedures where preventing hypothermia and providing patient securement are needed. The device is a thermal regulating system using a specially designed under-blanket that provides warmth, securement and resistance to patient movement. It can be used in all areas of a healthcare facility, but its primary use case will be for surgeries that place a patient in positions such as Trendelenburg or where the OR table is tilted where patient securement is of primary concern.

6. Indications for Use

The ThermAffyx™ Patient Safety System is intended to maintain normothermia, treat hypothermia and provide anti-slip positioning securement for patients.

The system is intended to be used by trained healthcare professionals in all areas of professional healthcare facilities.

It is indicated for use on adult patients.

7. Intended Use

The ThermAffyx™ Patient Safety System Patient is intended for use in all areas of healthcare facilities when there is a risk that the patient will not remain normothermic or become hypothermic and/or the patient is subject to traction or pulling forces caused by procedures that require special positioning like Trendelenburg.

The ThermAffyx™ Patient Safety System Warming and Positioning System is intended to maintain normothermia, treat hypothermia and provide anti-slip positioning securement for patients.

The system is intended to be used by trained healthcare professionals in all areas of professional healthcare facilities.

It is indicated for use on adult patients.

8. Predicate Comparison Table

Table I: System	Predicate device	Reference Device	Subject device	Comparison
Device/Trade Name	ASTOPAD® Patient Warming System	PrimePad ®	ThermAffyx™ Patient Safety System	NA
Classification **Product Code**	**DWJ** Thermal Regulating System (21 CFR §870.5900)	**LWG** Manual operating table and accessories and manual operating chair and accessories (21 CFR 878.4950)	**DWJ** Thermal Regulating System (21 CFR §870.5900) & **LWG** Manual operating table and accessories and manual operating chair and accessories (21 CFR 878.4950)	From a risk perspective, the subject device is a thermal regulating system (DWJ) with an under-blanket that provides extra patient stability and anti-slip securement according to product code LWG.
Class	Class II	Class I	Class II	Same as predicate
510(k) Number	K202197	510(k) exempt	K260278	NA
Indications for Use	The ASTOPAD® Patient Warming System is intended to prevent or treat hypothermia and to provide warmth to patients. The ASTOPAD® Patient Warming System is indicated for use in all areas of healthcare facilities for preventing or	For use in any procedure that requires Trendelenburg, Reverse Trendelenburg, or lateral positioning. Provides reliable support and stability with a next-generation, innovative, high-performance foam pad	The ThermAffyx™ Patient Safety System is intended to maintain normothermia, treat hypothermia and provide anti-slip positioning securement for patients. The system is intended to be used by trained healthcare	The indications for use are the same as the predicate device along with and added indication that the subject device provides anti-slip securement for the patient.

Table I: System	Predicate device	Reference Device	Subject device	Comparison
	treating hypothermia or maintaining normothermia. The warming blankets can be used over or under the patient (pediatric and adult) by appropriately trained healthcare professionals.		professionals in all areas of professional healthcare facilities. It is indicated for use on adult patients.	
Intended Use	The ASTOPAD® Patient Warming System is intended to prevent or treat hypothermia and to provide warmth to patients. The ASTOPAD® Patient Warming System is indicated for use in all areas of healthcare facilities for preventing or treating hypothermia or maintaining normothermia. The warming blankets can be used over or under the patient (pediatric and adult) by appropriately trained healthcare professionals.	For use in any procedure that requires Trendelenburg, Reverse Trendelenburg, or lateral positioning. Provides reliable support and stability with a next-generation, innovative, high-performance foam pad. PrimePad® Series material offers immediate rebound, anti-skid properties, enhanced breathability, and increased patient support.	The ThermAffyx™ Patient Safety System is intended for use in all areas of healthcare facilities when there is a risk that the patient will not remain normothermic or become hypothermic and/or the patient is subject to traction or pulling forces caused by procedures that require special positioning like Trendelenburg. The ThermAffyx™ Patient Safety System is intended to maintain normothermia, treat hypothermia and provide anti-slip positioning securement for patients. The system is intended to be used by trained healthcare professionals in all areas of professional healthcare facilities.	The overall intended use is the same as compared to the predicate: Both devices are intended to prevent or treat hypothermia. The subject device has a more limited use as it is intended to be used only under the patient. This limited use does not raise new or additional questions of safety or effectiveness. In addition, the subject device offers a new indication: the anti-slip positioning securement. This feature enhances the safety for the patient. The effectiveness of the warming function will not be impacted as will be shown in IEC 60601-2-35 tests that are planned for the subject device. It does not raise new or additional

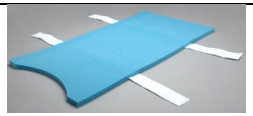
Table I: System	Predicate device	Reference Device	Subject device	Comparison
			It is indicated for use on pediatric and adult patients.	questions of safety or effectiveness. Further information is provided in Table III.
Type of Use	Prescription Use (Part 21 CFR 801 Subpart D)	OTC	Prescription Use (Part 21 CFR 801 Subpart D)	Same as the predicate.
Brief Device Description	 The ASTOPAD® Patient Warming System is a thermal regulating system which includes a connection cable that attaches to reusable conductive warming blankets for patient warming in clinical environments. The	 The PrimePad® is a new innovation in anti-skid patient positioning, offering a next-generation, innovative, high-performance foam pad. PrimePad offers excellent anti-skid properties, pressure reduction and patient support, providing confidence to the surgical team that the patient will remain immobile throughout the entire procedure.	 The ThermAffyx™ Patient Safety System is a thermal regulating system which includes a connection cable that attaches to single use conductive warming pad (“applied part”) for patient warming in clinical environments. The Pad will look similar to the reference device. The heating layer is between two layers of	The subject device and predicate device are based on the same technological principle; both are electrically powered and consist of a control unit and blanket(s) which can be connected to the controller. Both control units monitor the temperature and error conditions of the connected blanket. The subject device offers a new blanket feature with its anti-slip positioning securement, which is discussed in Table III below.

Table I: System	Predicate device	Reference Device	Subject device	Comparison
	system consists of a control unit (DUO310-NA) and one or optionally two applied parts (warming blankets/ COVXXX-NA) with different sizes to fit different applications.		foam. The foam is the same as used in the reference device. The system consists of a control unit and a pad that goes under the patient.	

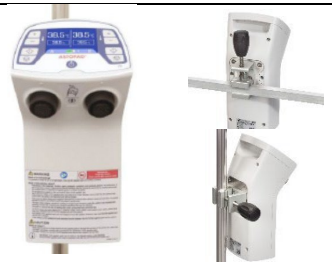
Table II: Control Unit	Predicate device	Reference Device	Subject device	Comparison
Type of Use	**Reusable**	NA	**Reusable**	Same
Comparison Technological Characteristics **Overall Construction**	 The ASTOPAD® control unit is equipped with a universal mounting clamp for attaching to standard medical equipment rails or an infusion stand, two outputs for connecting one or two	NA	 The ThermAffyx™ Patient Safety System control unit is equipped with a universal mounting clamp for attaching to standard medical equipment rails or an infusion stand, one	Same housing, same mounting clamp. Both control units are made from a plastic/metal combination. Subject device has one output only (for one applied part).

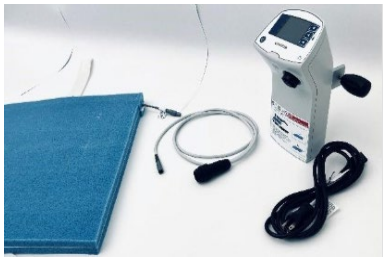
Table II: Control Unit	Predicate device	Reference Device	Subject device	Comparison
	applied parts, connection to mains by detachable power supply cord, connector for potential equalization, the electronic boards and the control panel for the user/operator.  (Complete System)		output for connecting one applied part,—connection to mains by detachable power supply cord, connector for potential equalization for the electronic boards and the control panel for the user/operator.  (Complete System) .	
Temperature Setting & Control	The desired temperature can be selected in the range of 32.0 °C - 39.0 °C in 0.5 °C increments for each connected applied part, independent of each other, on the control panel of the control unit. The control unit can also be used with only one of the	NA	The desired temperature can be selected: LOW, MEDIUM, HIGH. (34°C, 37°C, 40°C) The selected level and the current temperature are indicated on the control panel.	Both devices do not control the patient's temperature, but the surface temperature of the blanket. Desired temperature can be selected within the allowed

Table II: Control Unit	Predicate device	Reference Device	Subject device	Comparison
	outputs, A or B. The selected set temperature and the current temperature are displayed individually for each applied part in the control panel. The control unit supplies the applied part(s) with electrical current (low voltage) and monitors and controls the temperature of the applied part(s). The ASTOPAD® control unit does not control or indicate the actual temperature of the patient, but rather only the actual temperature of the applied part.		The control unit supplies the applied part with electrical current (low voltage) and monitors and controls the temperature of the applied part. The ThermAffyx™ Patient Safety System control unit does not control or indicate the actual temperature of the patient, but rather only the actual temperature of the applied part.	range by buttons (applicable standard IEC 60601-2-35). The subject device offers 3 levels of temperature (LOW, MEDIUM, HIGH. (34°C, 37°C, 40°C) which simplifies the operation by the user and does not raise new or additional questions of safety or effectiveness.
Alarm/Error Conditions	When error conditions occur, the control unit draws the operator's attention to the error condition by means of alarm signals (optical & acoustical). In the event of failure conditions (overheating, heater defect, sensor defect), the control unit reacts immediately by shutting off the power supply to the applied part.	NA	When error conditions occur, the control unit draws the operator's attention to the error condition by means of alarm signals (optical & acoustical). In the event of failure conditions (overheating, heater defect, sensor defect), the control unit reacts immediately by shutting off the power supply to the applied part.	Same
Battery Option	Optionally the control unit can be fitted with a battery. When the battery is installed, it is possible	NA	No battery option	Different

Table II: Control Unit	Predicate device	Reference Device	Subject device	Comparison
	to operate the device independently from the mains for approximately two hours.			The battery function of the predicate device is optional. Not having a battery option does not affect the safety and effectiveness of the subject device. The device will be tested to the applicable electrical safety standards.

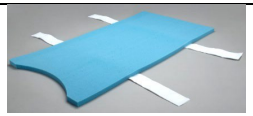
Table III: Blanket/Pad	Predicate device	Reference Device	Subject device	Comparison
Type of use	Reusable after reprocessing	Single-Use, not sterile	Single-Use, not sterile	It is the same as the reference device. The foam is required as this provides for the anti-slip feature. The foam cannot be cleaned and disinfected to allow repeated use.
Comparison Technological Characteristics **Construction**	The applied part consists of several layers of materials with integrated heating element.	 One layer foam with integrated straps on the bottom side to fix it to the OR table.	 The applied part consists of two layers of foam with an integrated heating element between and with integrated straps on the bottom side. The nature of the foam prevents sliding of the patient on the operating table. Additionally, the pad will be fixed to the operating table by straps.	Both blankets have integrated surface heating elements which ensure uniform heating. Both are subject to the same applicable safety standards for medical devices (IEC 60601-1, IEC 60601-2, IEC 60601-2-35, ISO 10993), which will be tested by independent and accredited test laboratories. The coefficient of friction of the foam of the subject device offers the same anti-slip feature as the reference product. Both heating elements are encapsulated within a foil to protect it against environmental influences like moisture and liquids.
Patient contact	Blankets are not intended for direct skin contact. A thin waterproof and absorbent barrier shall always be used between applied part and patient.	Intended for direct intact skin contact	Intended for direct intact skin contact	Due to the direct skin contact for limited duration (≤24 h) the applicable endpoints of ISO 10993-1 and FDA Guidance need to be considered. Biocompatibility testing

Table III: Blanket/Pad	Predicate device	Reference Device	Subject device	Comparison
				according to the applicable ISO 10993-1 and ISO 10993-x standards will be carried out by independent and GLP approved laboratories, so that no new or additional questions of safety or effectiveness will arise.
Use of the applied part	The ASTOPAD® blankets can be used under or over the patient. 	The PrimePad is intended to be used under the patient. 	The ThermAffyx™ Patient Safety System Warming and Positioning System pads are intended to be used under the patient. 	The feature “anti-slip positioning securement” can only be provided when the pad is placed under the patient. Therefore (and because of the definition in the applicable standard IEC 60601-2-35), the blanket is a so-called ‘under-blanket’. Warming patients from underneath by heated blankets, pads or mattresses is common use and in the scope of the IEC 60601-2-35. The subject device will conform with the requirements of this standard (tests will be carried out by independent accredited laboratories), to ensure safety and effectiveness are not affected.

Table III: Blanket/Pad	Predicate device	Reference Device	Subject device	Comparison
Variants of applied parts	COV070-NA warming blanket, 680x480 mm  COV105-NA warming blanket, 1050x500 mm  COV150-NA warming blanket, 1500x500 mm  COV155-NA Arm-chest-warming blanket, 1500x500 mm (with cut-outs)  COV180-NA warming blanket 1800x800 mm 	The reference device comes in various sizes. The size specified for use for surgeries in Trendelenburg is 44“ x 23“	ThermAffyx™ Heated Securement Pad is 44” x 23” (1118 mm x 584 mm)	The different sizes of the predicate device are offered to enable a more suitable use as over-blankets. The 44"x 23" of the subject device is the dimension of the portion of the OR table/mattress that goes from the patient's sacrum to the top edge beyond the patient's head. These dimensions ensure the patient is always in contact with the pad instead of having direct contact with the OR mattress. There are no new questions of safety or effectiveness regarding the size of the blanket as it is within the sizes offered by the predicate and reference device. Thermal safety and performance will be tested according to the applicable standard IEC 60601-2-35 and the anti-slip feature will be tested in comparison with the reference device to demonstrate safety and effectiveness.
Thickness	~ 30 mm (1.2”)	1 inch (25.4 mm)	~ 32 mm (1.25”)	Similar

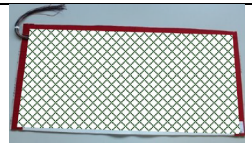
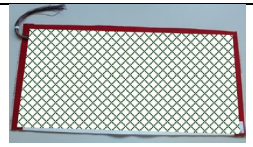
Table III: Blanket/Pad	Predicate device	Reference Device	Subject device	Comparison
Operating Principle	Resistive heating element	Non-active	Resistive heating element	Same
Heating Element	 fiber mesh	NA	 fiber mesh	Both heating elements are similar and use the technology of resistive heating or ohmic heating. This is the process by which electrical energy is converted into thermal energy when an electric current flows through a material with resistance. Both heating elements are subject of the same mechanical, electrical and thermal requirements which will be tested by independent and accrediated laboroties according to the standards IEC 60601-1 and IEC 60601-2-35 so that no new or additional questions of safety or effectiveness will arise.
Temperature Control/Sensors	Temperature regulation and control of the applied part is performed with in the heating element integrated sensors.	NA	Temperature regulation and control of the applied part is performed with in the heating element integrated sensors.	Same
Electrical Connection	Low voltage provided by Switch mode power supply	NA	Low voltage provided by Switch mode power supply	Same

Table III: Blanket/Pad	Predicate device	Reference Device	Subject device	Comparison
Anti Slip	No Anti-slip feature	Anti-slip feature	Anti-slip feature	The subject device uses the same foam as the reference device. Thanks to its higher coefficient of friction the foam offers the same anti-slip feature as the reference device. The heating performance is not affected by the foam and the risk of patient slipping when the operating table is tilted is reduced. Performance Testing shows the heating and the anti-slip functionality in comparison to the predicate and reference device are substantially equivalent.

9. Voluntary Standards

- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION
  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes
- ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- IEC 60601-2-35 Edition 2.1 2023-12 CONSOLIDATED VERSION Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use
- IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION Medical devices - Part 1: Application of usability engineering to medical devices
- ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices
- ISTA 3A 2018 Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb.) or Less

10. Non-Clinical Tests performed

- Performance Testing:
  - Bench Testing: Patient securement and Anti-Slip Testing
  - Testing per: IEC 60601-2-35 Particular requirements for heating devices using blankets, pads or mattresses
  - Coefficient of Friction Testing Pad on Skin
  - Coefficient of Friction Testing Pad on Bed
  - Coefficient of friction Testing comparison between Subject Device and Reference Device.
- Biocompatibility: Cytotoxicity, Irritation, Delayed Sensitization per respective ISO 10993 standard
- Electrical Safety Testing: per IEC 60601-1
- Alarms Testing: per IEC 60601-1-8
- EMC Testing: per IEC 60601-1-2 for electromagnetic compatibility
- Usability Testing: per IEC 62366 and IEC 60601-1-6.
- Software Testing: per IEC 62304
- Accelerated Aging Testing: per ASTM F1980
- Transportation Testing : per ISTA 3A
- Cleaning and Disinfection per FDA Guidance , Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Document issued on March 17, 2015, and AAMI TIR 12:2020/(R) 2023 Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Medical Device Manufacturers, 17 September 2020

11. Conclusions drawn from the non-clinical tests.

The results of the non-clinical tests demonstrate the ThermAffyx® Patient Safety System meets its Intended use. The device is biocompatible, capable of warming and securing the patient, and meets the latest electrical and EMC standards. The usability testing showed that users can use the device as intended.

12. Substantial Equivalence

The ThermAffyx™ Patient Safety System is substantially equivalent to the predicate device and reference device. Differences between the subject device and predicate device with the reference device were tested and shown not to raise any questions of safety and effectiveness.