DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 28, 2014

Smith Medical ASD, Inc.
Jim Johnson
Regulatory Specialist
1265 Grey Fox Road
St. Paul, Minnesota 55112

Re: K141686
Trade/Device Name: Equator Convective Warmer
Snuggle Warm Adult Full Body Convective Warming Blanket
Snuggle Warm Pediatric Full Body Convective Warming Blanket
Snuggle Warm Upper Body Convective Warming Blanket
Snuggle Warm Lower Body Convective Warming Blanket
Snuggle Warm Tube Convective Warming Blanket
Snuggle Warm Sterile Cardiac Convective Warming Blanket
Snuggle Warm Pediatric Under Body Convective Warming Blanket
Snuggle Warm Small Upper Body Convective Warming Blanket
Snuggle Warm Large Pediatric Under Body Convective Warming Blanket
Snuggle Warm Adult Under Body Convective Warming Blanket
Snuggle Warm Left Lateral Access Convective Warming Blanket
Snuggle Warm Right Lateral Access Convective Warming Blanket
Snuggle Warm Full Body Split Access Convective Warming Blanket
Snuggle Warm Multi-Access Convective Warming Blanket
Snuggle Warm Poncho Blanket Convective Warming Blanket
Snuggle Warm Adult Under Body Convective Warming Blanket with Arm Openings
Regulation Number: 21 CFR 870.5900
Regulation Name: Convective Warming System
Regulatory Class: Class II
Product Code: DWJ
Dated: June 20, 2014
Received: October 1, 2014

Dear Jim Johnson,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141686

Device Name
Equator® Convective Warmer and Snuggle Warm® Convective Warming Blanket

Indications for Use *(Describe)*

The Equator® Convective Warmer is intended to prevent and treat hypothermia when temperature therapy is clinically indicated. The warmer can also be used to provide thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Equator® Convective Warmer can be used with adult or pediatric patients and is intended for use by appropriately trained healthcare professionals in clinical environments.

The Snuggle Warm® Convective Warming Blanket is intended to prevent and treat hypothermia when temperature therapy is clinically indicated. The warming blanket can also be used to provide thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Snuggle Warm® Convective Warming Blanket can be used with adult or pediatric patients and is intended for use by appropriately trained healthcare professionals in clinical environments

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

smiths medical
bringing technology to life

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510(k) Summary

510(k) _K141686_____

DATE PREPARED: September 22, 2014

I. GENERAL INFORMATION

Applicant's Name and Address:	Smiths Medical ASD, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	Jim Johnson Regulatory Affairs Specialist
Common/Usual Name:	1) Convective Warming System
Trade Name:	1) Equator® Convective Warmer 2) Snuggle Warm® Convective Warming Blanket
Equivalence Device Comparison:	1) Snuggle Warm® 4000 Convective Warming System 2) Level 1® Snuggle Warm® Convective Warming Blankets 3) Level 1® Snuggle Warm® Pediatric Convective Warming Blankets 4) Level 1® Snuggle Warm® Sterile Cardiac Blanket (a component of Snuggle Warm® 4000 Convective Warming System) 5) Bair Hugger® Temperature Management System

II. DEVICE DESCRIPTION

Equator® Convective Warmer

The Equator® Convective Warmer (convective warmer) draws ambient- temperature air through a 0.2 micron particulate air filter. The filtered air is warmed to a selected temperature. The warmed air enters the convective warming blanket (blanket) through the hose and is distributed through delivery channels. Perforations on the patient side of the

air delivery channels in the convective warming blanket gently disperse the warmed air over and around the patient.

The convective warmer has three outlet temperature settings, which provide flexibility in patient treatment: 36°C, 40°C, and 44°C. These temperature settings are servo-controlled by a thermistor placed at the end of hose where the hose connects to the blanket. A fourth temperature setting delivers ambient-temperature air. The temperature indicated on the control panel is the temperature of air being delivered to the blanket at the end of the hose. A control thermistor in the convective warmer adjusts the power applied to the heater to maintain the selected temperature. This enables the system to maintain the selected temperature under variations in ambient temperature.

A safety thermistor provides a signal to a separate high-temperature analog circuit. The safety thermistor activates and causes an alarm if the temperature exceeds the set point. The analog safety circuit provides an independent means of shutoff, which discontinues power to the heater and motor. This prevents patient exposure to excessive temperatures. Patient contact is not applicable to convective warmers, warmer accessories, or warmer spare parts, as there is no direct patient exposure.

Snuggle Warm® Convective Warming Blankets

All testing was conducted with currently marketed Snuggle Warm® Convective Warming Blankets identified as product numbers with the prefix **"SW-"** followed by a four digit identifier. The proposed convective warming blankets listed in this submission are identical in material, design, and manufacturing process to the blankets to which the testing has been conducted and only the Indications For Use are different. The proposed convective warming blankets listed in this submission have the product numbers with the prefix **"SWU-"** followed by the same four digit identifier as the currently marketed convective warming blankets. Because the proposed blankets are identical in every nature to the currently marketed blankets with the exception of the Indications For Use, additional testing of the proposed blankets was not repeated and any testing that was conducted on the currently marketed blankets would be applicable to the proposed blankets.

The proposed Snuggle Warm® convective warming blanket in this submission (SWU-2001, SWU-2002, SWU-2003, SWU-2004, SWU-2007, SWU-2009, SWU-2010, SWU-2011, SWU-2013, SWU-2014L, SWU-2014R, SWU-2016, SWU-2018, SWU-2019, and SWU-2113) is a single-use disposable blanket consisting of two layers of non-woven polypropylene fabric coated with a layer of polyethylene. The layers are bonded together to form a distribution network of air delivery channels. The warm air is distributed around the blanket through the delivery channels and exits the blanket through a specially designed series of perforations in the patient side of the blanket. The distribution of air is designed to minimize temperature differences throughout the blanket. The convective warming blankets are not sterilized with the exception of the Sterile Cardiac Convective Warming Blanket (SWU-2008) described below. The convective warming blankets are compatible with competitor warming units if used in conjunction with a Smiths Medical ASD, Inc. adapter as described in the Adapter section below.

Patient contact applies to the convective warming blankets as with any other standard blanket or sheet. Exposure is limited to intact skin and/or breached or compromised (closed surgical wounds) surfaces only.

No product in the convective warming family contains latex, DEHP or BPA.

Snuggle Warm® Sterile Cardiac Convective Warming Blanket

The Snuggle Warm® Sterile Cardiac Convective Warming Blanket (SWU-2008) is identical in material and construction to the convective warming blankets listed in the preceding section. The only difference between the Snuggle Warm® Sterile Cardiac Convective Warming Blanket all other Snuggle Warm® Convective Warming Blankets is that the Sterile Cardiac Convective Warming Blanket is sterilized using a routine Ethylene Oxide (EO) sterilization cycle developed to deliver a sterility assurance level of 10^{-6} and meets ISO standards for EO residuals prior to release for distribution.

Adapters

Snuggle Warm® Convective Warming Blankets have been designed to be used with all Smiths Medical ASD, Inc. warmers without requiring the use of any adapter. Snuggle Warm® Convective Warming Blankets are compatible with other convective warmers

with the use of an adapter to ensure proper fit between the blanket and the warmer. The compatible warmers require the following for use with Snuggle Warm® convective warming blankets: (fpm=feet per minute, mpm = meters per minute).

Compatible Warmer Performance Requirements.

Minimum Flow Rate	Maximum Flow Rate	Minimum Temp	Maximum Temp	Minimum Hose Diameter	Maximum Hose Diameter
1541 fpm 470 mpm	2500 fpm 762 mpm	Ambient	113°F 45°C	2.625 inches 66.675 mm	3.125 inches 79.375 mm

The adapters are available from Smiths Medical ASD, Inc. are made from natural acetyl copolymer material and are designed to fit compatible warmer hose ends using the adapters (SWU-9001, SWU-9002, SWU-9003, SWU-9004). To ensure proper securement, a Level 1® elbow nozzle, included with each adapter, must be used to connect the convective warming blanket to the warmer. Adapters are designed to connect the Level 1® elbow nozzle to a compatible warming unit's hose. Each Snuggle Warm® Convective Warming Blanket IFU describes which adapter to use for compatible warming units.

III. DEVICE INTENDED USE

Equator® Convective Warmer

The Equator® Convective Warmer is intended to prevent and treat hypothermia when temperature therapy is clinically indicated. The warmer can also be used to provide thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Equator® Convective Warmer can be used with adult or pediatric patients and is intended for use by appropriately trained healthcare professionals in clinical environments.

Snuggle Warm® Convective Warming Blanket

The Snuggle Warm® Convective Warming Blanket is intended to prevent and treat hypothermia when temperature therapy is clinically indicated. The warming blanket can also be used to provide thermal comfort when conditions exist that may cause patients to

become too warm or too cold. The Snuggle Warm® Convective Warming Blanket can be used with adult or pediatric patients and is intended for use by appropriately trained healthcare professionals in clinical environments.

IV. SUMMARY OF STUDIES

Performance Testing

Performance tests and results for the Snuggle Warm® Convective Warming Blankets and the Equator® Convective Warmer are documented by Smiths Medical engineering test reports and independent test house reports. Human-factors engineering studies were also completed.

Clinical Studies

Human clinical studies were deemed unnecessary to evaluate the safety or effectiveness of the Equator® Convective Warmer and Snuggle Warm® Convective Warming Blankets.

Testing Conclusion

All testing met pre-established specifications, and successfully demonstrated that the devices performed as intended. The testing results allowed for a conclusion to be made that the Equator® Convective Warmer and Snuggle Warm® Convective Warming Blankets were as safe and effective as the predicate devices.

V. STATEMENT OF EQUIVALENCE

The Equator® Convective Warmer and Snuggle Warm® Convective Warming Blankets are substantially equivalent to the predicate devices, based on comparisons of the device classifications, intended use, and technological characteristics. Verification and validation tests confirmed the suitability of the devices for their intended uses. The test results did not raise new safety or performance questions, and confirmed that the Equator® Convective Warmer and Snuggle Warm® Convective Warming Blankets devices are substantially equivalent to the predicate devices.

VI. Subject and Predicate Device Comparison Tables

Table 3.6.1: Comparison between Snuggle Warm® Convective Warming Blankets and predicate devices.

Parameters	Predicate devices Snuggle Warm Convective Warming Blankets (models SW-2001, SW-2002, SW-2003, SW-2004) Per 510(k) K011907	Predicate devices Snuggle Warm Convective Warming Blankets (models SW-2013, SW-2014L, SW-2014R, SW-2016, SW-2018, SW-2019) Per 510(k) K083336	Proposed devices Snuggle Warm Convective Warming Blankets (models SWU-2001, SWU-2002, SWU-2003, SWU-2004, SWU-2007, SWU-2010, SWU-2013, SWU-2014L, SWU-2014R, SWU-2016, SWU-2018, SWU-2019, SWU-2113)
INTENDED USE	Convective warming system for thermal regulation of a patient's body temperature in a clinical environment.	Convective warming system for thermal regulation of a patient's body temperature in a clinical environment.	Convective warming system for thermal regulation of a patient's body temperature in a clinical environment.
INDICATIONS FOR USE	The Convective Warming System is intended for thermal regulating a patient's temperature to prevent hypothermia by a warm air heated blanket system to reduce cold discomfort during and after surgical procedures. It is intended for use by appropriately trained healthcare professionals in clinical environments.	The Convective Warming System is intended for thermal regulating a patient's temperature to prevent hypothermia by a warm air heated blanket system to reduce cold discomfort during and after surgical procedures. It is intended for use by appropriately trained healthcare professionals in clinical environments.	The Snuggle Warm® Convective Warming Blanket is intended to prevent and treat hypothermia when temperature therapy is clinically indicated. The warming blanket can also be used to provide thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Snuggle Warm® Convective Warming Blanket can be used with adult or pediatric patients and is intended for use by appropriately trained healthcare professionals in clinical environments.

Parameters	Predicate devices Snuggle Warm Convective Warming Blankets (models SW-2001, SW-2002, SW-2003, SW-2004) Per 510(k) K011907	Predicate devices Snuggle Warm Convective Warming Blankets (models SW-2013, SW-2014L, SW-2014R, SW-2016, SW-2018, SW-2019) Per 510(k) K083336	Proposed devices Snuggle Warm Convective Warming Blankets (models SWU-2001, SWU-2002, SWU-2003, SWU-2004, SWU-2007, SWU-2010, SWU-2013, SWU-2014L, SWU-2014R, SWU-2016, SWU-2018, SWU-2019, SWU-2113)
MATERIAL/DESIGN	• Consists of two layers of non-woven polypropylene fabric bonded to a fusion layer of polyethylene. • The layers are bonded together to form a distribution network of air delivery channels • The warm air is distributed around the patient's body through the delivery channels and exits the blanket through a specially designed series of perforations in the patient side layer of the blanket. • The distribution of air is designed to minimize temperature differences of delivered air at different blanket locations. • Two (2) hose ports for models SW-2001, SW-2003, and SW-2004. • The hose entry retainer material is 240# bleached white skin board un-laminated with high porosity and is 0.024" thick.	• Consists of two layers of non-woven polypropylene fabric bonded to a fusion layer of polyethylene. • The layers are bonded together to form a distribution network of air delivery channels • The warm air is distributed around the patient's body through the delivery channels and exits the blanket through a specially designed series of perforations in the patient side layer of the blanket. • The distribution of air is designed to minimize temperature differences of delivered air at different blanket locations. • Three (3) hose ports for model SW-2013. • The hose entry retainer material is 240# bleached white skin board un-laminated with high porosity and is 0.024" thick.	Identical Identical Identical Identical Identical Identical

Parameters	Predicate devices Snuggle Warm Convective Warming Blankets (models SW-2001, SW-2002, SW-2003, SW-2004) Per 510(k) K011907	Predicate devices Snuggle Warm Convective Warming Blankets (models SW-2013, SW-2014L, SW-2014R, SW-2016, SW-2018, SW-2019) Per 510(k) K083336	Proposed devices Snuggle Warm Convective Warming Blankets (models SWU-2001, SWU-2002, SWU-2003, SWU-2004, SWU-2007, SWU-2010, SWU-2013, SWU-2014L, SWU-2014R, SWU-2016, SWU-2018, SWU-2019, SWU-2113)
Packaging	Box and polybag	Box and polybag	Identical
Shelf Life	3 years	3 years	Identical
Sterility	Non-sterile	Non-sterile	Identical
SAFETY SPECIFICATION			
Blanket material conforms to 16CFR1610	Pass	Pass	Pass
Average Contact Surface Temperature of blanket shall not exceed 46°C in Normal Condition	Pass	Pass	Pass
Maximum Contact Surface Temperature of blanket shall not exceed 48°C in Normal Condition	Pass	Pass	Pass

Parameters	Predicate devices Snuggle Warm Convective Warming Blankets (models SW-2001, SW-2002, SW-2003, SW-2004) Per 510(k) K011907	Predicate devices Snuggle Warm Convective Warming Blankets (models SW-2013, SW-2014L, SW-2014R, SW-2016, SW-2018, SW-2019) Per 510(k) K083336	Proposed devices Snuggle Warm Convective Warming Blankets (models SWU-2001, SWU-2002, SWU-2003, SWU-2004, SWU-2007, SWU-2010, SWU-2013, SWU-2014L, SWU-2014R, SWU-2016, SWU-2018, SWU-2019, SWU-2113)
For connectors intended to accept Hoses, means shall be provided to prevent Hoses from disengaging unintentionally from connectors	Pass	Pass	Pass
PHYSICAL SPECIFICATIONS			
Material/design	• No Level 1 logo • Drape included (SW-2003, SW-2010, and SW-2013)	• Preprinted Level 1 logo on the top layer • Drape included (SW-2018)	• Preprinted logo on the top layer of all blankets • Drape included (SWU-2003, SWU-2010, SWU-2013, SWU-2018, and SW-2113) • SWU-2113 includes arm slots

Parameters	**Predicate devices** Snuggle Warm Convective Warming Blankets (models SW-2001, SW-2002, SW-2003, SW-2004) Per 510(k) K011907	**Predicate devices** Snuggle Warm Convective Warming Blankets (models SW-2013, SW-2014L, SW-2014R, SW-2016, SW-2018, SW-2019) Per 510(k) K083336	**Proposed devices** Snuggle Warm Convective Warming Blankets (models SWU-2001, SWU-2002, SWU-2003, SWU-2004, SWU-2007, SWU-2010, SWU-2013, SWU-2014L, SWU-2014R, SWU-2016, SWU-2018, SWU-2019, SWU-2113)
Blanket Dimensions Width X Length (approximate)	SW-2001: 40.00” X 78.75” SW-2002: 40.00” X 57.5” SW-2003: 80.0” X 40.0” SW-2004: 40.00” X 64.50”	SW-2013: 40.00: X 80.00” SW-2014L: 40.00” X 79.50” SW-2014R: 40.00” X 79.50” SW-2016: 40.00” X 80.00” SW-2018: 40.00” X 80.00” SW-2019: 40.00” X 80.00”	SWU-2001: 40.00” X 78.75” SWU-2002: 40.00” X 57.5” SWU-2003: 80.0” X 40.0” SWU-2004: 40.00” X 64.50” SWU-2007: 28.0” X 70.0” SWU-2010: 78.00” X 30.70” SWU-2013: 40.00: X 80.00” SWU-2014L: 40.00” X 79.50” SWU-2014R: 40.00” X 79.50” SWU-2016: 40.00” X 80.00” SWU-2018: 40.00” X 80.00” SWU-2019: 40.00” X 80.00” SWU-2113: 40.00” X 80.00”

Table 3.6.2: Comparison between Snuggle Warm® Pediatric Convective Warming Blankets and predicate devices.

Parameters	Predicate devices Snuggle Warm Pediatric Convective Warming Blankets (models SW-2009, SW-2011) Per 510(k) K061513	Proposed devices Snuggle Warm Pediatric Convective Warming Blankets (models SWU-2009, SWU-2011)
INTENDED USE	Thermal regulation of a patient's temperature in a clinical environment.	Convective warming system for thermal regulation of a patient's body temperature in a clinical environment.
INDICATIONS FOR USE **(Refer to Appendix A below)**	For thermal regulation of a patient's temperature to prevent hypothermia and/or reduce cold discomfort during and after surgical procedures. It is intended for use by appropriately trained healthcare professionals in clinical environments.	The Snuggle Warm® Convective Warming Blanket is intended to prevent and treat hypothermia when temperature therapy is clinically indicated. The warming blanket can also be used to provide thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Snuggle Warm® Convective Warming Blanket can be used with adult or pediatric patients and is intended for use by appropriately trained healthcare professionals in clinical environments.
MATERIAL/DESIGN	• Consists of two layers of non-woven polypropylene fabric bonded to a fusion layer of polyethylene. • The layers are bonded together to form a distribution network of air delivery channels • The warm air is distributed around the patient's body through the delivery channels and exits the blanket through a specially designed series of perforations in the patient side layer of the blanket. • The distribution of air is designed to minimize temperature differences of delivered air at different blanket locations. • The blanket is designed to be placed under the patient. • The hose entry retainer material is 240# bleached white skin board un-laminated with high porosity and is 0.024" thick.	Identical Identical Identical Identical Identical Identical
Packaging	Box and polybag	Identical
Shelf Life	3 years	Identical
Sterility	Non-sterile	Identical

Parameters	Predicate devices Snuggle Warm Pediatric Convective Warming Blankets (models SW-2009, SW-2011) Per 510(k) K061513	Proposed devices Snuggle Warm Pediatric Convective Warming Blankets (models SWU-2009, SWU-2011)
SAFETY SPECIFICATION		
Blanket material conforms to 16CFR1610	Pass	Pass
Average Contact Surface Temperature of blanket shall not exceed 46°C in Normal Condition	Pass	Pass
Maximum Contact Surface Temperature of blanket shall not exceed 48°C in Normal Condition	Pass	Pass
For connectors intended to accept Hoses, means shall be provided to prevent Hoses from disengaging unintentionally from connectors	Pass	Pass
PHYSICAL SPECIFICATIONS		
Material/design	• The blanket includes absorbent pads • Preprinted logo on top layer is the Snuggle Warm logo SnuggleRoo® • Ink for logo is Pantone 266 (Purple) • Two (2) hose inlets • Drape included • Full body is placed onto blanket	• The blanket includes absorbent pads • Preprinted logo on top layer is the Snuggle Warm logo SnuggleRoo® • Ink for logo is Pantone 266 (Purple) • Two (2) hose inlets • Drape included • Full body is placed onto blanket
Blanket Dimensions Width X Length (approximate)	SW-2009: 37.0” X 26.0” SW-2011: 53.75” X 40.25”	SWU-2009: 37.0” X 26.0” SWU-2011: 53.75” X 40.25”

Table 3.6.3: Comparison between Snuggle Warm® Cardiac Convective Warming Blankets and predicate devices.

Parameters	Predicate devices Snuggle Warm Convective Warming Blankets (models SW-2008) Per 510(k) K040632	Proposed devices Snuggle Warm Convective Warming Blankets (models SWU-2008)
INTENDED USE	Convective warming system for thermal regulation of a patient's body temperature in a clinical environment.	Convective warming system for thermal regulation of a patient's body temperature in a clinical environment.
INDICATIONS FOR USE **(Refer to Appendix A below)**	The device is intended for thermal regulating a patient's temperature to prevent hypothermia by a warm air heated blanket to reduce cold discomfort during and after surgical procedures.	The Snuggle Warm® Convective Warming Blanket is intended to prevent and treat hypothermia when temperature therapy is clinically indicated. The warming blanket can also be used to provide thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Snuggle Warm® Convective Warming Blanket can be used with adult or pediatric patients and is intended for use by appropriately trained healthcare professionals in clinical environments.
MATERIAL/DESIGN	• Consists of two layers of non-woven polypropylene fabric bonded to a fusion layer of polyethylene. • The layers are bonded together to form a distribution network of air delivery channels • The warm air is distributed around the patient's body through the delivery channels and exits the blanket through a specially designed series of perforations in the patient side layer of the blanket. • The distribution of air is designed to minimize temperature differences of delivered air at different blanket locations.	Identical Identical Identical Identical
Packaging	Box and polybag	Identical
Shelf Life	3 years	Identical
Sterility	Sterile	Identical
SAFETY SPECIFICATION		
Blanket material conforms to 16CFR1610	Pass	Pass

Parameters	Predicate devices Snuggle Warm Convective Warming Blankets (models SW-2008) Per 510(k) K040632	Proposed devices Snuggle Warm Convective Warming Blankets (models SWU-2008)
Average Contact Surface Temperature of blanket shall not exceed 46°C in Normal Condition	Pass	Pass
Maximum Contact Surface Temperature of blanket shall not exceed 48°C in Normal Condition	Pass	Pass
For connectors intended to accept Hoses, means shall be provided to prevent Hoses from disengaging unintentionally from connectors	Pass	Pass
PHYSICAL SPECIFICATIONS		
Material/design	• Packaging for sterile cardiac blanket consists of the Sterile Cardiac Blanket, Instructions for Use, and a Convective Warming Hose • All contents are packaged together in a sealed polybag • Package is Ethylene Oxide Sterilized to 10^{-6} SAL.	• Packaging for sterile cardiac blanket consists of the Sterile Cardiac Blanket, Instructions for Use, and a Convective Warming Hose • All contents are packaged together in a sealed polybag • Package is Ethylene Oxide Sterilized to 10^{-6} SAL.
Blanket Dimensions Width X Length(approximate)	SW-2008: 40.0” X 64.	SWU-2008: 40.0” X 64.5”

Table 3.6.4: Comparison between Equator® Convective Warmer and predicate devices.

Parameters	Predicate device Bair Hugger Model 750 Temperature Management Unit Per 510(k) K001149	Predicate device Snuggle Warm® 4000 Temperature Management System (model SW-4000) Per 510(k) K011907	Proposed device Equator® Convective Warmer (model EQ-5000)	Proposed device Equator® Convective Warmer (model EQ-5000HF)
INTENDED USE	Convective warming system for thermal regulation of a patient's body temperature in a clinical environment.	Convective warming system for thermal regulation of a patient's body temperature in a clinical environment.	Convective warming system for thermal regulation of a patient's body temperature in a clinical environment.	Convective warming system for thermal regulation of a patient's body temperature in a clinical environment.
PERFORMANCE				
Air Velocity	Up to 48 cfm or 23Lps (2233 ft/minute)	1800-2500 ft/minute (9.1-12.7 m/sec)	1650-2500 ft/minute (8.4-12.7 m/sec)	1650-2500 ft/minute (8.4-12.7 m/sec)
Air Temperature Four (4) selections: 1. High 2. Medium 3. Low 4. Ambient	Hose End Temperature 43°C +/- 1.5°C 38°C +/- 4.5°C 32°C +/- 1.5°C Ambient	Hose End Temperature 44°C +/- 1.0°C 40°C +/- 1.0°C 36°C +/- 1.0°C Ambient	Hose End Temperature 44°C +/- 1.0°C 40°C +/- 1.0°C 36°C +/- 1.0°C Ambient	Hose End Temperature 44°C +/- 1.0°C 40°C +/- 1.0°C 36°C +/- 1.0°C Ambient
System Power Requirements	110-120 VAC 50/60 Hz 11.7 Amps	120 VAC 60 Hz 8.9 Amps	115 VAC, 50/60 Hz 8.05 Amps	115 VAC, 50/60 Hz 8.05 Amps
Heater Power Requirement	1600 Watts	980 Watts	800W	800 W
PHYSICAL SPECIFICATIONS				
Dimensions	13.5" X 9.5" X 10.5"	20" X 13" X 16.5"	11.75" X 9.5" X 7.5"	11.75" X 9.5" X 7.5"
Weight	16.3 lbs	45 lbs	15 lbs	15 lbs
Materials	Plastic/metal	Plastic/ metal	Plastic/Metal	Plastic/Metal
SAFETY				
EMI/EMC Compliant	Yes, IEC 60601-1, EN 60601-1	Yes, EN 60601-1, EN 60601-1-2	Yes, IEC 60601-1, EN 60601-1-2	Yes, IEC 60601-1, EN 60601-1-2
Forced air Over Temperature Protection (44°C setting)	Thermal cutoff shuts heater off at 47°C +/- 2°C	Electrical Heater safety relay opens at 47.0°C +/- 1.0°C	Electrical Heater safety relay opens at 47.0°C +/- 1.0°C	Electrical Heater safety relay opens at 47.0°C +/- 1.0°C

Parameters	Predicate device Bair Hugger Model 750 Temperature Management Unit Per 510(k) K001149	Predicate device Snuggle Warm® 4000 Temperature Management System (model SW-4000) Per 510(k) K011907	Proposed device Equator® Convective Warmer (model EQ-5000)	Proposed device Equator® Convective Warmer (model EQ-5000HF)
Alternate provisions	Flashing amber light & audible alarm activated	Warning light & audible alarm activated	Warning light & audible alarm activated	Warning light & audible alarm activated
FEATURES				
Hose with Secure Locking Mechanism	Yes	Yes	Yes	Yes
Hose Support Arm/Handle	No	Yes	Yes	Yes
Air Filter	Replaceable 0.2 micron	Replaceable 0.2 micron	Replaceable 0.2 micron	Replaceable 0.2 micron
Temperature Display	Front panel LCD display	Front panel digital display	Front panel digital display	Front panel digital display