July 26, 2018

Smiths Medical ASD, Inc.
% Mark Job
Regulatory Technology Services, LLC
1394 25th Street, Nw
Buffalo, Minnesota 55313

Re: K181699
Trade/Device Name: Level 1 Convective Warmer
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II
Product Code: DWJ
Dated: June 25, 2018
Received: June 27, 2018

Dear Mark Job:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Fernando Aguel -S

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)*

K181699

Device Name
Level 1® Convective Warmer

Indications for Use *(Describe)*

The Level 1® 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 Level 1® Convective Warmer 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Date of Preparation:	July 20, 2018 (Revised)
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Trade Name(s):	Thermal Regulating System
Device Name(s)	Level 1® Convective Warmer
Device Classification	Class II
Regulation Number and Product Codes	21 CFR § 870.5900/ DWJ System, Thermal Regulating

Purpose

The purpose of this premarket notification Traditional 510(k) is to establish substantial equivalence and obtain FDA Clearance for the Level 1® Convective Warmer which is intended to prevent and treat hypothermia when temperature therapy is clinically indicated.

This submission addresses the introduction of a microprocessor to the subject device to control the monitoring and adjustments of air flow, heating, temperature, and alarms where the predicate device, Equator® Convective Warmer, uses discrete digital and analog circuitry.

Primary Predicate Device

The primary predicate device for this submission is the currently marketed Smiths Medical Equator® Convective Warmer.

Primary Predicate Device Name	Product Code	FDA 510k Number Clearance Date
Equator Convective Warmer	DWJ	K141686 Cleared on October 28, 2014

General Device Description:

The Level 1® Convective Warmer, is a forced air thermal regulating systems which includes a connection hose to attach to the Snuggle Warm® Convective Warming Blankets for patients requiring body temperature regulation in clinical environments which are provided non-sterile and intended to be reused. In order to accommodate various clinical environments, the Level 1® Convective Warmer is able to be placed on the floor, placed on a floor cart, or mounted on an I.V. pole to allow flexible portability. The Level 1® Convective Warmer is used with the Snuggle Warm® Convective Warming Blankets.

Indications for Use:

The Level 1® 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 Level 1® Convective Warmer can be used with adult or pediatric patients and is intended for use by appropriately trained healthcare professionals in clinical environments.

Summary of Technological Characteristics:

The subject device, *Level 1® Convective Warmer*, shares the same technological characteristics as the cleared FDA 510(k) predicate device, Equator® Convective Warmer. These characteristics include the same intended use, same clinical application, same overall design, and the same convective warming principle of operation by drawing ambient air through a filtered opening then

heating to the desired temperature for convective warming therapy. Both warmers are forced air heating devices that help to regulate a patient's body temperature and are used with the Snuggle Warm® Convective Warming Blankets.

The difference, however, is that the subject device uses a microprocessor (software) to control, monitor and adjust air flow, heating, temperature, and alarms where the predicate device controls the same outputs through discrete digital and analog circuitry, containing no software.

Also, this submission incorporates three (3) non-significant changes: operating noise level, air temperature settings, and heater power wattage.

Summary of Performance Testing:

The *Level 1® Convective Warmer* incorporates the same indications for use and the same technological characteristics as the legally marketed predicate device, Equator® Convective Warmer, FDA cleared under K141686, issued October 28, 2014.

Non-clinical testing of the *Level 1® Convective Warmer* was assessed and tested as a system, including the subject device, connection hose and Snuggle Warm® Convective Warming Blanket, appropriately to design controls; i.e. design verification, design validations. The test results conclude the *Level 1® Convective Warmer* to be substantially equivalent to the predicate device, Equator® Convective Warmer (EQ-5000HF).

Testing is listed below:

- Electrical Safety and Electromagnetic Compatibility testing was conducted per IEC 60601-1 and IEC 60601-1-2 respectively to ensure that the device performs safely under normal use conditions. All requirements were met.
- Particular Safety Testing was completed per IEC 80601-2-35 to ensure the device meets basic safety and essential performance of heating devices using blankets, pads or mattresses in medical use. All requirements were met.
- Safety testing was conducted per IEC 60529 to ensure the level of protection by enclosures meet the specified IP12 rating. The requirement was met.
- Design Validation / Human Factors per IEC 62366 was conducted to ensure the subject device performance is acceptable for its intended use. All requirements were met.
- System validation testing for compatibility with warming blankets was performed to ensure function. All requirements were met.
- Bench testing was conducted to ensure the device meets the System Requirements Specification in DP-0003-938. All requirements were met.

Substantial Equivalence

Smiths Medical considers the subject device, *Level 1® Convective Warmer,* performance to be substantially equivalent to the predicate device, Equator® Convective Warmer (EQ-5000HF), based on the performance test results.

There are no significant differences in intended use, mechanical and functional performance and functional scientific technology, except the difference of the addition a microprocessor software control mechanism for the *Level 1® Convective Warmer*. Smiths Medical demonstrates through performance testing that no new issues of safety and effectiveness are raised due to the change of the subject device's control mechanism. Both the subject and predicate devices are used to treat the same clinical condition and represent a same principle of operation.

Level 1® Convective Warmer compared to Equator® Convective Warmer

Substantial Equivalence Comparison Table			
Parameter	**Subject Device Level 1 Convective Warmer (L1-CW-120V)**	**Predicate device Equator Convective Warmer (EQ-5000HF)**	**Comparison**
REGULATORY INFORMATION			
FDA Product Code	DWJ System, Thermal Regulating	DWJ System, Thermal Regulating	SAME
FDA Regulation	21 CFR 870.5900	21 CFR 870.5900	SAME
Classification	Class II	Class II	SAME
Indication for Use	The Level 1® 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 Level 1® Convective Warmer can be used with adult or pediatric patients and is intended for use by appropriately trained healthcare professionals in clinical environments.	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.	SAME

Substantial Equivalence Comparison Table			
Parameter	**Subject Device Level 1 Convective Warmer (L1-CW-120V)**	**Predicate device Equator Convective Warmer (EQ-5000HF)**	**Comparison**
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.	SAME
TECHNICAL SPECIFICATIONS			
Air Flow Rate via hose sans blanket	44CFM @0.4 inches H_2O back pressure	43CFM @0.4 inches H_2O back pressure	SIMILAR
Air Temperature Settings	43 ± 1.0 °C 40 ± 1.0 °C 37 ± 1.0 °C Ambient	44 ± 1.0 °C 40 ± 1.0 °C 36 ± 1.0 °C Ambient	DIFFERENT
System Power Requirement	115VAC, 50/60 Hz	115VAC, 50/60 Hz	SAME
Heater Power Requirement	950 Watts	800 Watts	DIFFERENT
Dimensions	15.3"x11.0"x12.6"	11.75" X 9.5" X 7.5"	SIMILAR
Weight	13.7 lbs.	15 lbs.	SIMILAR
Materials of construction	Plastic/Metal	Plastic/Metal	SAME
Power On Self-Test	Yes	Yes	SAME
SAFETY			
Basic Electrical Safety	IEC 60601-1	IEC 60601-1	SAME
EMI/EMC Compliant	IEC 60601-1-2	IEC 60601-1-2	SAME
Basic Safety and Essential Performance for Heating Devices	IEC 80601-2-35	IEC 80601-2-35	SAME
Forced Air Over Temperature Protection	Electrical Heater Safety Relay opens at 47.0 ± 1°C	Electrical Heater Safety Relay opens at 47.0 ± 1°C	SAME
Control Mechanism	Microprocessor with software	Discrete digital and analog circuitry	DIFFERENT
FEATURES			
Air Filter	Replaceable 0.2 micron	Replaceable 0.2 micron	SAME
Operating noise level	42dBA	53dBA	DIFFERENT

Substantial Equivalence Comparison Table			
Parameter	**Subject Device Level 1 Convective Warmer (L1-CW-120V)**	**Predicate device Equator Convective Warmer (EQ-5000HF)**	**Comparison**
Device Photo			N/A
Used with the Snuggle Warm® Convective Warming Blankets	Yes	Yes	SAME

Conclusion

Smiths Medical concludes that the *Level 1® Convective Warmer* is for use with Snuggle Warm® Convective Warming Blankets for patients requiring body temperature regulation being that it is substantially equivalent to the predicate device, thermal regulating system indications (DWJ), and does not raise new questions of safety risks imposed on the patient or the device user.

Smiths Medical's evaluation concludes the subject device, will perform substantially equivalent to the predicate devices.

Subject Device	Predicate	Predicate 510(k)
Level 1® Convective Warmer	Equator® Convective Warmer and Snuggle Warm® Convective Warming Blankets	K141686