April 29, 2021

3M Company
Hilary Hovde
Regulatory Affairs Specialist
2510 Conway Ave.
St. Paul, Minnesota 55144

Re: K210605
Trade/Device Name: 3M™ Bair Hugger™ Universal Warming Gown made with Thinsulate™ Insulation
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: February 26, 2021
Received: March 1, 2021

Dear Hilary Hovde:

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,

Nicole Gillette
Assistant Director (Acting)
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.

Submission Number *(if known)*

Device Name

3M™ Bair Hugger™ Universal Warming Gown made with Thinsulate™ Insulation

Indications for Use *(Describe)*

The 3M™ Bair Hugger™ Universal Warming Gown made with Thinsulate™ Insulation is part of the 3M patient temperature management system ('the system') when used with Bair Hugger™ 700 series or 675 warming unit. The system, monitored and controlled by a trained clinician, is used perioperatively to prevent and treat hypothermia.

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 for 3M™ Bair Hugger™ Universal Warming Gown made with Thinsulate™ Insulation

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3M Health Care
2510 Conway Ave.
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact: Hilary B. Hovde
Regulatory Affairs Specialist
Phone Number: (651) 736-0364

Submission Date: February 26, 2021

Device Name and Classification

Trade Name:	3M™ Bair Hugger™ Universal Warming Gown made with Thinsulate™ Insulation
Common/Usual Name:	Thermal Regulating System
Device Classification:	Class II
Classification Name:	Thermal Regulating System [21 CFR § 870.5900, DWJ]

Predicate Device

3M™ Bair Hugger™ Model 675 Total Temperature Management System, K171373

Reference Devices

Bair Paws® Temperature Management System, K060865

Indications for Use

The 3M™ Bair Hugger™ Universal Warming Gown made with Thinsulate™ Insulation is part of the 3M patient temperature management system ('the system') when used with Bair Hugger 700 series or 675 warming unit. The system, monitored and controlled by a trained clinician, is used perioperatively to prevent and treat hypothermia.

Description of Device

The 3M™ Bair Hugger™ Universal Warming Gown made with Thinsulate™ Insulation is a disposable, single-patient perioperative warming gown with 3M™ Thinsulate™ Insulation. The warming gown is intended to be worn throughout the entire perioperative journey: before, during and after surgery.

Bair Hugger™ warming gowns are part of the Bair Hugger™ warming system; there are two parts to the system: the warming gown and warming unit (temperature management unit). The Universal Warming Gown is available in three sizes (small, standard, and x-large) and is intended to be used with the Bair Hugger™ 700 series or 675 warming unit. The system, monitored and controlled by a trained clinician, is used perioperatively to prevent and treat hypothermia.

The warming gown has two patient warming options: an integrated lower body insert and a removable multi-position warming blanket. The lower body insert has a lower midline hose port,

and the warming blanket is to be removed from a pocket in the front upper section of the gown. The warming blanket can be used alone or in combination with the warming gown during surgery.

After surgery, the warming gown should be re-donned and used to warm the patient using the lower midline hose port.

Comparison of Technological Characteristics with the Predicate and Reference Devices

The 3M™ Bair Hugger™ Universal Warming Gown made with Thinsulate™ Insulation was shown to be substantially equivalent to the 3M™ Bair Hugger™ Model 675 Total Temperature Management System cleared per K171373. 3M™ Bair Hugger™ Warming Gowns are part of the 3M™ Bair Hugger™ Temperature Management System; there are two parts to the system: the warming gown and warming unit (temperature management unit). This 510(k) is for a new warming gown which incorporates a layer of Thinsulate™ Insulation to provide added insulation. There is no change to the patient warming unit part of this system. Safety and efficacy of the new warming gown was demonstrated through biocompatibility testing and performance testing with the gown and unit used as a system as intended.

Substantial Equivalence and Summary of Studies

The difference between the subject and predicate device has been evaluated through performance and biocompatibility tests to provide evidence of substantial equivalence for the 3M™ Bair Hugger™ Universal Warming Gown made with Thinsulate™ Insulation.

The device performance was verified through the following tests:

- Thermal Performance Testing per IEC-80601-2-35

Device samples passed the following biocompatibility tests performed in accordance with ISO 10993-1, *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process* as recognized by FDA. The 3M™ Bair Hugger™ Universal Warming Gown made with Thinsulate™ Insulation is categorized as a surface contacting device, with intact skin contact of limited duration (≤ 24 hours) in accordance with ISO 10993-1 and FDA Guidance, *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process."* The battery of tests included the following:

- Cytotoxicity
- Sensitization
- Irritation

Conclusion

Based on the intended use, technological characteristics, performance data, and non-clinical tests performed, the subject device is substantially equivalent to the 3M™ Bair Hugger™ Model 675 Total Temperature Management System (cleared under K171373), Class II, product code DWJ and does not raise new questions of safety or effectiveness.