March 30, 2021

3M Company
Brian Kleiber
Regulatory Affairs Specialist
3M Center, 2510 Conway Ave.
Bldg. 275-5W-06
St. Paul, Minnesota 55144

Re: K210603
Trade/Device Name: 3M™ Bair Hugger™ Temperature Management System (Model 675)
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 Brian Kleiber:

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,

for Fernando Aguel
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.

Submission Number *(if known)*

K210603

Device Name

3MTM Bair HuggerTM Temperature Management System, Model 675

Indications for Use *(Describe)*

The Bair Hugger temperature management system is intended to prevent and treat hypothermia. In addition the temperature management system can be used to provide patient thermal comfort when continuations exist that may cause patients to feel too warm or too cold. The temperature management system can be used with adult and pediatric 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.

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

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510(k) Summary

Sponsor Information:

3M Company
3M Center,2510 Conway Ave.
Building 275-5W-06
St. Paul, MN 55144-1000

Contact Person: Brian Kleiber, Regulatory Specialist
Phone Number: (651) 737-0195
FAX Number: (651) 737-5320
eMail Address: bkleiber@mmm.com

Date of Summary: February 24, 2021

Device Name and Classification:

Common or Usual Name	Patient warming system
Proprietary Name	3M™ Bair Hugger™ Temperature Management System, Model 675
Classification Name	Thermal regulating system (21 CFR § 870.5900)
Device Classification	Class II
Product Code	DWJ

Predicate Device:

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

Description of Device:

The 3M™ Bair Hugger™ Temperature Management System, Model 675 consists of a Model 675 portable warming unit (with optional rolling cart) along with a 3M Bair Hugger warming blanket or warming gown. The Bair Hugger warming unit provides forced warm air using an electrical resistance heater, fan/blower and a user control interface. Warmed air flows from the warming unit into a Bair Hugger warming blanket or warming gown by means of a flexible connecting hose. The Bair Hugger warming blanket or warming gown is placed over, around or underneath the patient. Small perforations in the blanket or gown allows the forced warm air to be gently dispersed over a patient's skin to prevent and treat hypothermia, and/or to provide patient thermal comfort. The warming unit may be controlled to provide only ambient (non-warmed) air.

Indications for Use:

The Bair Hugger temperature management system is intended to prevent and treat hypothermia. In addition, the temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to feel too warm or too cold. The temperature management system can be used with adult and pediatric patients.

Comparative Data for Determining Substantial Equivalence of the New Device to the Predicate Device:

Information provided in this 510(k) submission, documents that the 3M™ Bair Hugger™ Temperature Management System, Model 675 has the same technological characteristics (i.e. same design, energy source) as the predicate device. In addition, nonclinical testing to IEC 80601-2-35, *Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use* documents that the 3M™ Bair Hugger™ Temperature Management System, Model 675 provides the same warming performance and safety as compared to the predicate device. Additional software upgrades have been made.

Conclusion:

The 3M™ Bair Hugger™ Temperature Management System, Model 675 meets all applicable standards, has equivalent technological characteristics, and has equivalent warming performance and safety features when compared to the predicate device. The 3M™ Bair Hugger™ Temperature Management System, Model 675 performs as well as the predicate device. There are no new questions of safety or effectiveness.