October 10, 2017

3M Company
Jon Platt
Regulatory Affairs Manager
3M Center, Building 275-5W-06
St. Paul, Minnesota 55144

Re: K171373
Trade/Device Name: 3M Bair Hugger Model 675 Total Temperature Management System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II
Product Code: DWJ
Dated: July 7, 2017
Received: July 12, 2017

Dear Jon Platt:

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 (DICE) 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 (DICE) 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,

Nicole G. Ibrahim -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)*

K171373

Device Name
3M Bair Hugger Model 675 Total Temperature Management System

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 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.

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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5.0 510(k) Summary

Sponsor Information:

3M Health Care
3M Center, Building 275-5W-06
St. Paul, MN 55144-1000

Contact Person: Jon Platt, Regulatory Affairs Manager
Phone Number: (651) 736-1850
FAX Number: (651) 737-5320
eMail Address: jcplatt1@mmm.com

Date of Summary: October 10, 2017

Device Name and Classification:

Common or Usual Name	Patient warming system
Proprietary Name	3M™ Bair Hugger™ Model 675 Total Temperature Management System
Classification Name	Thermal regulating system (21 CFR § 870.5900)
Performance Standards	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*

Predicate Device:

Augustine Medical Bair Hugger Model 750 Total Temperature Management System, K001149.

Relevant chronological information regarding the predicate device

- K001149 was cleared on September 6, 2000 by Augustine Medical.
- In 2003 the Augustine Medical company name was changed to Arizant.
- In October 2010 3M purchased Arizant. 3M is the current owner of this 510(k) and the Bair Hugger™ brand name and its products.

Equivalent Marketed Device:

Augustine Medical Bair Hugger Temperature Management System K021473.

Description of Device:

The 3M™ Bair Hugger™ Model 675 Total Temperature Management System 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™ Model 675 Total Temperature Management System has the same technological characteristics (i.e. same design, materials, chemical composition, and energy source) as the predicate device. In addition, nonclinical bench 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™ Model 675 Total Temperature Management System provides the same warming performance and same safety features as the predicate device.

Conclusion:

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