K021473

JUL 9 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted by

Augustine Medical, Inc.
10393 West 70th Street
Eden Prairie, MN 55344

Contact person: Scott Augustine, MD
Chief Executive Officer

Telephone: 952-947-1200
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Device name

Trade name: Bair Hugger® temperature management system (Bair Hugger Series 200, 500, and 700 forced-air temperature management units used with Bair Hugger blankets) and Model 459 patient cooling set.

Common/usual name: Hyper/Hypothermia system

Classification name: System, Thermal, Regulating DWJ

Predicate Devices

1. Augustine Medical, Bair Hugger® Model 600 Hyper/hypothermia unit used with Bair Hugger blankets.
2. Seabrook Medical Systems, Tropi-Cool Hyper/hypothermia unit used with Temp-pad blankets.

Device Description

The Bair Hugger temperature management system consists of:

- a portable forced-air temperature management unit (200, 500, or 700 series),
- a disposable Bair Hugger forced-air blanket (various models), and
- the Model 459 patient cooling set (new disposable component of the system).

The temperature management unit delivers warmed or room-temperature air directly to a Bair Hugger blanket via a flexible hose, or it delivers room-temperature air to the Model 459 patient cooling set, which, when filled with common ice, cools the air before delivering it to a Bair Hugger blanket. Depending on the blanket model used, the blanket

Device Description (continued)

is placed around, over, or underneath the patient. Small perforations in the patient-side of the blanket disperse the air over the patient.

The new disposable Model 459 patient cooling set consists of an ice receptacle (flexible plastic bag) with an attached flexible hose assembly. The patient cooling set also has a handle to allow hanging it on an IV pole or similar stand near the temperature management unit.

The ice receptacle has:

- a hose port that accepts the hose of a Bair Hugger® temperature management unit,
- a resealable opening for adding and retaining ice,
- a valve for draining meltwater, and
- an integral divider that directs the flow of room-temperature air from the temperature management unit through the ice, which cools the air to a temperature ranging between 3.5°C and room temperature, as required.

Indications for use

The Bair Hugger temperature management system is indicated for hyper- or hypothermic patients or normothermic patients for whom induced hyper- or hypothermia or localized temperature therapy is clinically indicated. In addition, the Bair Hugger temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Bair Hugger temperature management system can be used with adult and pediatric patients.

Description of Safety and Effectiveness

Performance testing of the Model 459 patient cooling set was conducted to demonstrate the effectiveness of the component when used with the other Bair Hugger temperature management system components. The performance testing indicates that room-temperature air flowing from a temperature management unit through the ice-filled patient cooling set would be cooled to less than 10°C for about 1 hour. Ice may be added to the patient cooling set to prolong cooling therapy. A temperature management unit may also deliver ambient temperature air directly to a blanket for cooling therapy.

Because the modification to the device does not change any of the safety features of the device, testing was done only to determine the safety of temperatures delivered by the Model 459 patient cooling set, the new disposable component of the device.

The delivered temperatures are safe for two reasons: first, the temperature of air delivered to a Bair Hugger blanket is limited by the temperature and duration of the ice added to the Model 459 patient cooling set. Most ice in clinical settings is produced and stored in an icemaker at 0°C, and performance testing indicates that 15 pounds of ice will only deliver temperatures under 10°C for about an hour before the temperatures begin to rise. Second, tests show that if users add ice that has been stored below 0°C to the patient cooling set, the temperature of the delivered air might initially drop to close to 0°C, but it will quickly rise and stabilize between 5°C and 10°C, the standard temperature range for the device. The few minutes that a patient may be exposed to temperatures below 5°C are not harmful to the patient.

Substantial equivalence

The modified Bair Hugger® temperature management system (including the new Model 459 patient cooling set) is substantially equivalent to the predicate devices in safety and effectiveness. The modified device has the same intended use and patient population as the predicate devices. The warming modes of the previously cleared device(s) are not affected by the modification so the comparison of the device to predicate devices focuses on the substantial equivalence of the cooling modes of the devices.

Substantial equivalence to the Bair Hugger Model 600 hyper/hypothermia unit

The modified Bair Hugger temperature management system and the Bair Hugger Model 600 hyper/hypothermia unit (first predicate device) use the same technology to deliver air to forced-air blankets. The only significant difference between the two devices is that, in the cooling mode, the modified Bair Hugger temperature management system uses an external, ice-filled component (Model 459 patient cooling set) to cool the air before delivering it to a Bair Hugger blanket, and the predicate device has a thermoelectric heat exchanger that cools air and delivers it directly to a Bair Hugger blanket. This difference has no negative effect on the safety and effectiveness of the modified device because the temperatures delivered to the patient are similar.

Substantial equivalence to the Tropi-Cool hyper/hypothermia unit

The only significant difference between the modified Bair Hugger temperature management system (modified device) and the Tropi-Cool hyper/hypothermia unit (second predicate device) is that, in the cooling mode, the modified device uses an external, ice-filled component (Model 459 patient cooling set) to cool air before delivering it to a Bair Hugger forced-air blanket. The predicate device has a thermoelectric heat exchanger that cools water and delivers it directly to a Temp-pad water pad. This difference has no negative effect on the safety and effectiveness of the modified device because the temperatures delivered to the patient are similar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 9 2002

Augustine Medical, Inc.
c/o Scott Augustine, MD
Chief Executive Officer
10393 West 70th Street
Eden Prairie, MN 55344

Re: K021473
Trade Name: Bair Hugger® Temperature Manager System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: May 7, 2002
Received: May 8, 2002

Dear Dr. Augustine:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

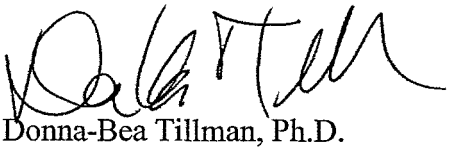
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) number (Traditional): K021473

Device name: Augustine Medical, Inc. Bair Hugger® temperature management system

Indications for use: The Bair Hugger temperature management system is indicated for hyper- or hypothermic patients or normothermic patients for whom induced hyper- or hypothermia or localized temperature therapy is clinically indicated. In addition, the Bair Hugger temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Bair Hugger temperature management system can be used with adult and pediatric patients.

PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over the Counter Use _____

(Per 21 CFR 801-109)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices
510(k) Number K021473