F. 510(k) Summary of Safety & Effectiveness

APR 30 1998

This 510(k) Summary of Safety & Effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The device is a Class II device called the Bair Hugger® Blood/Fluid Warmer.

K973741

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

Date prepared: September 10, 1997

Trade/Proprietary Name: Bair Hugger® Blood/Fluid Warmer

Common/Usual Name: Blood/Fluid Warmer

Classification Name: Warmer, Thermal, Infusion Fluid

Predicate Devices: Dupaco Counterflo 300, Augustine Medical Bair Hugger® 241® Fluid Warming Set

Description of Device

The Bair Hugger Blood/Fluid Warmer consists of a warming device and a disposable set. The warming device is designed to warm blood, blood products, and intravenous liquids at flow rates of up to and including 500 ml/min. The Bair Hugger Blood/Fluid Warmer can deliver temperatures as high as and including 42°C, (temperatures in accordance with the American Association of Blood Banks (AABB) Standards for Blood Banks and Transfusion Services).

Two types of sterile disposable sets are available. The disposables are composed of the same materials used in the predicate devices. The fluid warming bag, attached to the disposable set, is placed inside the warming device and contacts heated aluminum plates. Blood, blood products, and liquids pass through the warming bag and are heated as they flow through. The warming device controls the temperature of the aluminum plates, which are heated by means of electrical resistance. The device meets the requirements of UL 2601, IEC 601-1, and EN 60601.

Intended Use

The Bair Hugger Blood/Fluid Warmer is intended to warm blood, blood products, and liquids.

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Comparison of the Technological Characteristics of the New Device and Predicate Devices

The Bair Hugger® Blood/Fluid Warmer is substantially equivalent to the Dupaco Counterflo 300 Blood/Fluid Warmer (BK950038) and the Bair Hugger® 241 Fluid Warming Set (BK940032).

Comparison of Technological Features

Feature	Bair Hugger Blood/Fluid Warmer	Dupaco Counterflo 300	241 Fluid Warming Set
Flow rates	KVO - 500 ml/min	15 to 300 ml/min	0 - 50 ml/min
Method of Operation	Metal plate heated by electrical resistance; disposable bag contacts plate	Metal plate heated by electrical resistance; disposable bag contacts plate	Hose conduit heated by forced air; disposable tubing surrounded by heated air
Electronics	PID-controlled	PID-controlled	Electronically controlled
Temperature Control	Thermocouples	RTD sensor	User adjustable set point; thermocouple
Alarms	Audible and visual over and under temperature; alarms activate when temperature is at 32°C, at 43° C, and at 46°C.	Audible and visual over and under temperature alarms; alarms activate when temperature is below 34°C, and at 42° and 43-44.5°.	Audible and visual over temperature alarms; alarms activate when temperature reaches 53°C.

Discussion of Nonclinical Studies

Studies were conducted to evaluate the hemolytic effect of heat on RBCs while flowing through the Bair Hugger Blood/Fluid Warmer. Percent hemolysis was evaluated during flow and stop flow conditions. Minimal damage to RBCs was demonstrated; the results were not clinically significant.

Conclusion

The Bair Hugger Blood/Fluid Warmer has similar technological characteristics, components, and materials, and the same intended use as devices currently on the market. Therefore, because of the similarities to the predicate devices, Augustine Medical believes this new device does not raise any new safety or effectiveness issues.

Contact: Scott D. Augustine, M.D., CEO
Augustine Medical, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 1998

Scott D. Augustine, MD
Augustine Medical
10393 West 70th Street
Eden Prairie, Minnesota 55344 USA

Re: K973741
Trade Name: Bair Hugger Blood/Fluid Warmer
Regulatory Class: II
Product Code: BSB
Dated: February 11, 1998
Received: February 12, 1998

Dear Dr. Augustine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number: Not known

Device name: The Bair Hugger® Blood/Fluid Warmer

Indications for use:

The Bair Hugger Blood/Fluid Warmer is intended to warm blood, blood products, and liquids.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973741

Prescription Use X or Over the Counter Use _____
(Per 21 CFR 801-109)