JAN 11 2002

K014121

510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name: Nellcor Puritan Bennett, Inc.

Submitter's Address: 4280 Hacienda Drive
Pleasanton, CA 94588-8604

Contact Person: Anthony Mullin
Phone Number: 314-654-3049
FAX Number: 314-654-3344

Summary Date: December 5, 2001

Device Trade Name: WarmTouch® CareQuilt™ Cardiac Blanket

Common Name: Convective Air Warming Blanket

Device Classification Names: The FDA has classified Thermal Regulation Systems as Class II devices under CFR Title 21, Section 870-5900. The product code is DWJ

Predicate Devices: CareDrape™ Lower Body Blanket, Cat #503-0830
CareQuilt™ Full Body/ Multi-Access Warming Blanket, Cat #503-0810.

Device Description: The WarmTouch® CareDrape™ Cardiac Blanket is similar to the CareDrape™ Lower Body Blanket in use, as both are used in the operating room to help manage the patient's body temperature. The WarmTouch® CareDrape™ Cardiac Blanket is similar to the CareQuilt™ Full Body/ Multi-Access Warming Blanket, as both are equipped with slits, which can be opened for access to the patient through the blanket. The key difference between the Cardiac Blanket and all earlier WarmTouch® blankets is that the Cardiac Blanket is sterile permitting use of the blanket within the sterile field.

Indications For Use: The WarmTouch Patient Warming System (warming unit and blanket) is intended for prevention and treatment of hypothermia and/or shivering in the critical care environment.

Contraindications: There are no contraindications for the use of this device

Summary of Performance Testing:

- ***Maximum Temperature delivered to the patient***
  The blankets were tested according to the draft ASTM standard Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management Devices. This testing verified that the blanket maintained a maximum temperature of 40.5°C. This maximum temperature is located immediately in front of the nozzle tube.

- ***Temperature range***
  The blankets were tested according to the draft ASTM standard Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management Devices. This testing verified that the blanket maintained a temperature difference of <5°C across its area.

- ***Burst Pressure – Pre/post sterilization and aging***
  The Burst Pressure of the blankets was tested in the same way as the currently marketed WarmTouch blankets. The blankets are inflated until they burst, and the burst pressure measured. The cardiac blankets met the same robustness requirements as do the predicate blankets.

- ***Tape strength – pre/post sterilization and aging***
  The tensile strength of the tape bond was measured before and after accelerated aging (2 year equivalent) and after 3 levels of radiation exposure. These levels bracket the typical sterilization dosages. Aging and sterilization have minimal negative effects on the tape adhesive.

Conclusions:

The WarmTouch® CareDrape™ Cardiac Blanket performs as intended according to its performance specification. The WarmTouch® CareDrape™ Cardiac Blanket is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2002

Mr. Anthony M. Mullin
Assistant Director, Regulatory and Clinical Affairs
Nellcor Puritan Bennett, Inc.
4280 Hacienda Drive
Pleasanton, CA 94588

Re: K014121
Trade Name: WarmTouch® CareDrape™ Cardiac Blanket
Regulation Number: 21 CFR 870.5900
Regulation Name: Convective Air Warming Blanket
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: December 6, 2001
Received: December 17, 2001

Dear Mr. Mullin:

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.

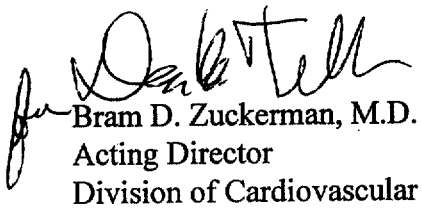
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
And Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K014121

Device Name: WarmTouch® CareDrape™ Cardiac Blanket

Indications for Use:

The WarmTouch Patient Warming System (warming unit and blanket) is intended for prevention and treatment of hypothermia and/or shivering in the critical care environment.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K014121

Prescription Use ✓ OR Over-the-Counter Use _____

(Per 21 CFR 801.109)