

**tyco**

Healthcare

**Nellcor**

APR 23 2002

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KO 20604

## 510(k) Summary

**Submitted by:** Nellcor Puritan Bennett Incorporated  
(A business unit of Mallinckrodt Inc.,  
a division of Tyco Healthcare Group LP)  
4280 Hacienda Drive  
Pleasanton, CA 94588

**Company Contact:** Gina To  
Senior Regulatory Affairs Project Manager  
(925) 463-4427  
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**Date Summary Prepared:** February 22, 2002

**Trade Name:** WarmTouch Model 5300 Patient Warming System

**Common/Usual Name:** Convective Air Warming System

**Classification Name:** Thermal Regulating System per 21 CFR §870.5900

**Product Code:** DWJ

**Legally Marketed Predicate Device (Unmodified):** WarmTouch, Advanced Warming Systems, Inc.,  
510(k) #K913016

### Device Description

The WarmTouch Model 5300 Patient Warming System surrounds the patient with warm air and convectively transfers heat across the skin. With the WarmTouch Model 5300 Patient Warming System, air is warmed and delivered into a lightweight blanket (*CareQuilt* or *CareDrape* Blanket) that rests over or under the patient.

The modification to the WarmTouch Patient Warming Unit consists of design changes relating to temperature settings.

### Intended Use

The WarmTouch Model 5300 Patient Warming System (warming unit and blanket) is intended for prevention and treatment of hypothermia, for example, with the surgical patient, the patient in the pre-operative holding area, the pregnant woman who shivers during epidural anesthesia due to hypothermia, or any patient who is uncomfortable anywhere in the cold critical care environment.

## **Summary of Technological Characteristics of the Device Compared to the Legally Marketed (Unmodified) Device**

The WarmTouch Model 5300 Patient Warming System has the same technological characteristics as the above referenced predicate device. The only changes relate to temperature settings.

### **Testing**

Performance testing of the WarmTouch Model 5300 with the *CareQuilt* and *CareDrape* Blankets demonstrated safe maximum temperature compliance.

Testing of the WarmTouch Model 5300 Patient Warming System for electrical safety and EMC testing demonstrated compliance to applicable sections in the November 1993 FDA Review Guidance document, UL544 Standard for Safety for Medical and Dental Equipment, IEC 60601-1-2:1993 1st Edition requirements, IEC 60601-2-35 Particular Standard for Patient Warming Systems, and CAN/CSA C22.2 No. 125 for Electromedical Equipment. Performance testing demonstrated conformity to the draft ASTM Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management Devices.

### **Conclusions**

The WarmTouch Model 5300 Patient Warming System and the results of testing do not raise new questions of safety or effectiveness when compared to the legally marketed predicate device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 23 2002

Ms. Gina To  
Senior Regulatory Affairs Project Manager  
Nellcor Puritan Bennett Incorporated  
4280 Hacienda Drive  
Pleasanton, CA 94588

Re: K020604

Trade Name: WarmTouch Model 5300 Patient Warming System  
Regulation Number: 21 CFR 870.5900  
Regulation Name: Thermal Regulating System  
Regulatory Class: Class II (two)  
Product Code: DNJ  
Dated: March 27, 2002  
Received: March 28, 2002

Dear Ms. To:

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.

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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  
and Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K020604

Device Name: WarmTouch Model 5300 Patient Warming System

**Indications For Use:**

The WarmTouch Model 5300 Patient Warming System (warming unit and blanket) is intended for prevention and treatment of hypothermia, for example, with the surgical patient, the patient in the pre-operative holding area, the pregnant woman who shivers during epidural anesthesia due to hypothermia, or any patient who is uncomfortable anywhere in the cold critical care environment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Robert T. ...*  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K020604

(Optional Format 3-10-98)

Prescription Use X  
(Per 21 CFR 801.109)