K033021
p 1/2

NOV 1 2 2003

Section 14

Premarket Notification [510(k)] Summary

1. **Submitted by:**

Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, GA 30076

Contact Person: Richard V. Wolfe
Manager, Regulatory Affairs

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Date Prepared: September 25, 2003

2. **Device Name**

Trade / Proprietary Name: Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads
Common / Usual name: Hypo / Hyperthermia System
Classification Name: System, Thermal Regulating (per 21CFR 870.5900)

3. **Predicate Device**

The Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads is substantially equivalent to the MediVance Inc. ARTIC SUN™ Temperature Management System – Model 100 Control Unit and Energy Transfer Pads cleared under 510(k) # K002577.

4. **Intended Use of the Device**

The Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads is a thermal regulating system, indicated for monitoring and controlling patient temperature.

Clinical applications of this device include any condition where patient temperature control within a range covering mild hypothermia to normothermia is required. This would include, but not be limited to, medical, surgical, febrile, accidental hypothermia, or heat stroke patients.

5. **Description of the Device**

The Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads is a device used to monitor and control patient temperature. It consists of single-use heat transfer pads, which are adhered to areas of the patient's skin, and a control module that circulates temperature-controlled water. The control module is connected to the pads by flexible tubing. A commercially available probe connected to the control module senses the patient's core temperature. The system can control the patient's core temperature by altering the temperature of the circulating water.

K033021
p 2/2

Section 14

Premarket Notification [510(k)] Summary *(Continued)*

6. **Summary of the technological characteristics of the device compared to the predicate device**

The Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads is identical in design to MediVance's Artic Sun™ Temperature Management System which obtained FDA clearance on October 26, 2000 under 510(k) number K002577 Kimberly-Clark acquired all product rights related to the patient warming business from MediVance, Inc. on May 27, 2003

7. **Testing**

Testing of the Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads [under MediVance's 510(k) # K002577], included: biocompatibility testing in accordance with ISO 10993-1 and / or USP, electrical safety testing in accordance with IEC601 and functional safety and performance testing.

8. **Conclusions**

The Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads is the exact same medical device as MediVance's Artic Sun™ Temperature Management System which obtained FDA clearance on October 26, 2000. Therefore, no new safety or effectiveness issues exist.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 2003

Kimberly-Clark Corporation
c/o Mr. Richard V. Wolfe
1400 Holcomb Bridge Road
Roswell, GA 30076

Re: K033021
Kimberly-Clark Patient Warming System – Model 100
Control Unit and Energy Transfer Pads
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: September 25, 2003
Received: September 26, 2003

Dear Mr. Wolfe:

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), 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) you may obtain. 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.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 15

Indications For Use

Applicant: Kimberly-Clark Corporation

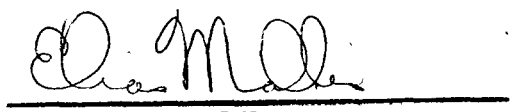
510(k) Number: K033021

Device Name: Kimberly-Clark Patient Warming System – Model 100 Control Unit and Energy Transfer Pads

Indications for Use: The KIMBERLY-CLARK* Patient Warming System is intended for monitoring and controlling patient temperature. The indications for use of the device include any condition where patient temperature control within the range covering mild hypothermia to normothermia is required.

(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 Cardiovascular Devices

510(k) Number K033021