DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 18, 2014

Medivance, Inc.
% Stacci Cronk
Senior Regulatory Specialist
321 South Taylor Avenue
Suite 200
Louisville, Colorado 80027

Re: K142702
Trade/Device Name: Arctic Sun Temperature Management System, ArcticGel Pads (Universal, XXS, XS, S, M and L), Small Universal ArcticGel Pad, Neonatal ArcticGel Pad
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: November 26, 2014
Received: November 28, 2014

Dear Stacci Cronk,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

510(k) Number: K142702

Device Name: Arctic Sun® Temperature Management System (including the ArcticGel™ pads)

Indications for Use: The Arctic Sun® Temperature Management System is a thermal regulating system, indicated for monitoring and controlling patient temperature in adult and pediatric patients of all ages.

Prescription Use: ☒ **or** **Over the Counter Use** ☐

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5: 510(k) Summary

The following information is provided as required by 21 CFR §807.92 for the Arctic Sun® Temperature Management System 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Sponsor:
Medivance, Inc.
A wholly owned subsidiary of C. R. BARD, Inc.
321 South Taylor Avenue, Suite 200
Louisville, CO 80027 USA

Contact:
Stacci Cronk, RAC
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Date Prepared: September 19, 2014

Trade Name: Arctic Sun® Temperature Management System (including the ArcticGel™ pads)
Common/Usual Name: patient temperature management system
Classification Name: system, thermal regulating
Regulation: 21 CFR §870.5900
Classification: II
Product Code: DWJ

Predicate Device(s):

Arctic Sun® Temperature Management System (including the ArcticGel™ pads)	Medivance, Inc.	K101092 K002577
Medi-Therm® Hyper/Hypothermia System (including Hyper/Hypothermia blanket(s)/body wrap(s))	Gaymar Industries Inc.	K100585

Device Description: The Arctic Sun Temperature Management System is a non-invasive, thermal regulating system that monitors and controls patient temperature within a range of 32°C to 38.5°C (89.6°F to 101.3°F). The Arctic Sun Temperature Management System consists of the Arctic Sun 5000 Control Module and disposable non-sterile ArcticGel Pads. The control module re-circulates temperature-controlled water to the ArcticGel Pads. A commercially-available medical temperature probe, such as naso-pharyngeal, bladder, rectal, or esophageal, connected to the control module senses the patient's core temperature. A control algorithm automatically adjusts the water temperature (automatic mode) or the clinician can adjust the water temperature (manual mode) to obtain the desired patient temperature.

The ArcticGel Pads come in various sizes to cover a broad range of patients and fit both males and females. Each pad has an inlet and an outlet connection that attaches to a fluid delivery line that is connected to the Arctic Sun 5000 Control Module. Up to six pads can be connected at one time. The pads adhere to the patient by the use of a biocompatible hydrogel adhesive

The Small Universal ArcticGel Pad and Neonatal ArcticGel Pad are modified versions of the current ArcticGel Pads and utilize an additional patient contacting fabric material.

Indications for Use: The Arctic Sun Temperature Management System is a thermal regulating system, indicated for monitoring and controlling patient temperature in adult and pediatric patients of all ages.

Substantial Equivalence: The Arctic Sun Temperature Management System (Arctic Sun 5000 Control Module and ArcticGel Pads) was shown to be substantially equivalent in indications for use, design, technological characteristics, materials and system features and functions to the predicate devices.

The Arctic Sun Temperature Management System (Arctic Sun 5000 Control Module and ArcticGel Pads) proposed Indications for Use is the same as the predicate Arctic Sun Temperature Management System with the addition of a defined patient population. The predicate Medi-Therm Hyper/Hypothermia System Indications for Use contains the proposed “adult and pediatric patients” verbiage.

The Small Universal ArcticGel Pad, Neonatal ArcticGel Pad and the predicate ArcticGel Pads and Gaymar Blankets are noninvasive surface temperature management devices. Additionally, the Small Universal and Neonatal ArcticGel Pads and the predicate ArcticGel Pads may be used in with the Arctic Sun Temperature Management System for use in continuous patient temperature monitoring and control.

The Small Universal ArcticGel Pad, Neonatal ArcticGel Pad and the predicate devices are manufactured from common biocompatible materials that are common to many disposable medical devices.

The Small Universal ArcticGel Pad, Neonatal ArcticGel Pad and the predicate devices are of similar sizes and weights, and provide similar cooling capacities and durations.

Biocompatibility and Performance Testing:
Biocompatibility testing performed in accordance with ISO 10993-1, 10993-05 and 10993-10 demonstrated the fabric material used on Small Universal ArcticGel Pad and Neonatal ArcticGel Pad to be non-cytotoxic, non-irritating and nonsensitizing.

Comparative performance testing demonstrated that the performance of the Small Universal ArcticGel Pad and Neonatal ArcticGel Pad is substantially equivalent to that of the predicate devices.

Conclusions: Based on the testing and comparison to the predicate devices, the Arctic Sun Temperature Management System (Arctic Sun 5000 Console and ArcticGel Pads) performs as intended, raises no new safety or effectiveness issues and is substantially equivalent to the predicate devices.