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

September 02, 2016

Medivance, Inc.
Stacci Cronk
Regulatory Affairs Manager
321 South Taylor Ave, Suite 200
Louisville, Colorado 80027

Re: K161602
Trade/Device Name: Arctic Sun Temperature Management System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: August 2, 2016
Received: August 3, 2016

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*
K161602

Device Name
Arctic Sun® Temperature Management System

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Arctic Sun® Temperature Management System

510(k) Owner: Medivance, Inc.
A wholly owned subsidiary of C. R. BARD, Inc.
321 South Taylor Avenue, Suite 200
Louisville, CO 80027 USA

Contact Person: Stacci Cronk, RAC
Regulatory Affairs Manager
Phone: 303-327-5151
E-mail: stacci.cronk@crbard.com

Date Prepared: June 2, 2016

Trade Name: Arctic Sun® Temperature Management System (Model 5000 Control Module)

Common/Usual Name: Patient temperature management system

Classification Name: Thermal regulating system

Regulation: 21 C.F.R. §870.5900

Classification: II

Product Code: DWJ

Predicate Device

Arctic Sun® Temperature Management System	Medivance, Inc.	K142702 K101092

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.

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.

Please note that this Special 510(k) Notice is specific to the Arctic Sun 5000 Control Module. The ArcticGel Pads are previously 510(k) cleared under K002577 and K142702 and are not the subject of the Special 510(k) Notice.

Purpose of Special 510(k) Notice

The purpose of this 510(k) is to modify the cleared Arctic Sun Temperature Management System by incorporating minor component, software and associated labeling changes.

Summary of Technical Characteristics Compared to the Predicate Device

The modifications to the Arctic Sun Temperature Management System do not change the intended use, indications for use, or fundamental scientific technology of the device. The Arctic Sun Temperature Management System (Model 5000) includes the following modifications:

- New alert and alarm (software change)
- Option to add two additional customizable protocols (software change)
- Data output capability for Electronic Medical Records (EMR) connectivity support (software change)
- System default changes
- User preference changes to the user interface (software change)
- New/modified components
- Labeling (new caution, new IFU for temperature simulator key, and various changes for clarifications and/or safer use of the device)

Performance Testing

The software for the Arctic Sun Temperature Management System was developed and is maintained in accordance with the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Device" (05/11/05) and "General Principles of Software Validation; Final Guidance for Industry and FDA Staff" (1/11/02). Hardware design verification and software validation of the Arctic Sun Temperature Management System was performed to verify all new system and software requirements, the result of which confirmed the function of the device modifications.

In addition to functional testing, the Arctic Sun Temperature Management System was retested, when applicable to confirm ongoing compliance with Electrical Safety and Electromagnetic Compatibility Standards.

Substantial Equivalence

The Arctic Sun Temperature Management System has the same Indications for Use, Intended Use and fundamental scientific technology as the predicate Arctic Sun Temperature Management System. The Arctic Sun Temperature Management System was shown to be substantially equivalent in indications for use, design, technological characteristics, materials, and system features and functions to the predicate device.

Conclusion

Based on the testing and comparison to the predicate device, the Arctic Sun Temperature Management System performs as intended, raises no new or different safety or effectiveness issues and is substantially equivalent to the predicate device.