K101092

# 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

## Premarket Notification [510(K)] Summary

(per 21 CFR 807.92)

**Company Name**
Medivance, Inc.
321 South Taylor Avenue, Suite 200
Louisville, Colorado 80027

JUL 13 2010

Contact Person: Lynne Aronson
Director, Regulatory Affairs and Quality Assurance
Telephone: 303-926-1917
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**Device Name**
Trade/Proprietary Name: Arctic Sun™ Temperature Management System, Model 2000
Common/Usual Name: Hypo/Hyperthermia System
Classification Name: System, Thermal Regulating (per 21 CFR 870.5900)

**Predicate Devices**
The Arctic Sun™ Temperature Management System, Model 5000, is substantially equivalent to the following predicate devices:

| | | |
|---|---|---|
| Arctic Sun Temperature Management System – Model 2000 | Medivance, Inc. | K010338, K071341 |

**Intended use of the device**
The Arctic Sun Temperature Management System is a thermal regulating system, indicated for monitoring and controlling patient temperature.

**Description of the Device**
The Arctic Sun Temperature Management System is a thermoregulatory device 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 System consists of the Arctic Sun Control Module and disposable ArcticGel Pads.

A patient temperature probe connected to the Control Module provides patient temperature feedback to an internal control algorithm which automatically increases or decreases the circulating water temperature to achieve a pre-set patient target temperature determined by the clinician.

The Arctic Sun pulls temperature-controlled water ranging between 4°C and 42°C (39.2°F and 107.6°F) through the ArcticGel Pads, resulting in heat exchange between the water and the patient.

**Summary of the technological characteristics of the device compared to the predicate device.**
The Arctic Sun Temperature Management System Model 5000 includes the following modifications:

- Changed user interface from a LCD with membrane switch to an integrated PC with color graphical user interface (GUI) and touch screen, which also provides for the following new device features:
- New streamlined industrial design of the console:
- Associated software modifications required to implement the new graphical user interface and console configuration.

**Testing**
Full system software, performance, functional, and inspection verifications were performed on the Arctic Sun Model 5000.

Design verification of the system requirements and software validation of the control and monitor processors software requirements involved repeating the same or similar testing conducted on the predicate Arctic Sun Model 2000. Additionally, design verification and software validation of the new control panel software requirements was performed that confirmed functionality of the new control panel graphic user interface and the associated software, as well as communications with the internal control and monitor processors.

The verification and validation test results demonstrate that the new control panel graphic user interface functions as designed and the Arctic Sun Model 5000 is safe and effective for its intended use.

**Conclusions**
Based upon the testing and comparison to the predicate device, the Arctic Sun Temperature Management System performs as intended and raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUL 16 2010

Medivance
c/o Ms. Lynne Aronson
Director, Regulatory Affairs and Quality Assurance
321 South Taylor Avenue
Suite 200
Louisville, CO 80027

Re: K101092
Arctic Sun® Temperature Management System – Model 5000 Control Unit
Regulation Number: 21 CFR 870.5900
Regulation Name: System, Thermal Regulating
Regulatory Class: Class II
Product Code: DWJ
Dated: June 1, 2010
Received: June 2, 2010

Dear Ms. Aronson:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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

Enclosure

# STATEMENT: INDICATION FOR USE

510 (k) Number: K101092

Device Name: Arctic Sun Temperature Management System

**Indications for Use:**

The Arctic Sun Temperature Management System is a thermal regulating system, indicated for monitoring and controlling patient temperature.

Prescription Use ___X__ Over the Counter Use _____
(Part 21 CFR 801 Subpart D) and/or (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]
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ion of Cardiovascular Devices

Number K101092