February 28, 2020

Medivance, Inc.
Jacquelyn Borinski
Regulatory Affairs Specialist
321 South Taylor Ave, Suite 200
Louisville, Colorado 80027

Re: K200225
Trade/Device Name: Arctic Sun Stat Temperature Management System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: January 29, 2020
Received: January 30, 2020

Dear Jacquelyn Borinski:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Fernando Aguel
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200225

Device Name
Arctic Sun™ Stat 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™ Stat Temperature Management System

510(k) Owner: Medivance, Inc.
321 South Taylor Avenue, Suite 200
Louisville, CO 80027 USA

Contact Person: Jacquelyn Borinski
Regulatory Affairs Specialist
Phone: 720-880-5343
E-mail: Jackie.Borinski@bd.com

Date of Submission: January 29, 2020

Subject Device Name: Arctic Sun™ Stat Temperature Management System

Subject Device

Device Trade Name : Arctic Sun Stat Temperature Management System
Common Name : Patient Temperature Management System
Regulation Name : Thermal Regulating System
Regulation Number : 21 C.F.R. 870.5900
Product Code : DWJ
Regulatory Class : II
Classification Panel : Cardiovascular
Prior Correspondence: none

Predicate Device

510(k) Number : K161602
Device Trade Name : Arctic Sun Temperature Management System
Common Name : Patient Temperature Management System
Regulation Name : Thermal Regulating System
Regulation Number : 21 C.F.R. 870.5900
Product Code : DWJ
Regulatory Class : II
Classification Panel : Cardiovascular
Prior Correspondence: none

Device Description

The Arctic Sun Stat 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 system consists of the Arctic Sun Stat Control Module, associated accessories, and is used with the ArcticGel Pads. The Arctic Sun Stat Control Module and associated accessories are the subject of this submission. The Arctic Sun Stat Control Module circulates temperature-controlled water ranging between 4°C and 40°C (39.2°F and 104°F) through the ArcticGel Pads, resulting in heat exchange between the water and the patient. A commercially available YSI 400 series compatible patient temperature probe connected to the Arctic Sun Stat 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 Stat Control Module has the option to provide secure data output of device monitoring values; there is no patient-identifiable information. The data output functions, including USB, RS-232, and Wi-Fi, do not allow the user to write to the device and are intended for user convenience only.

Indications for Use of the Subject Device

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.

Indications for Use of the Predicate Device

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.

Comparison of Indications for Use to the Predicate Device

The indications for use statement for the subject device, the Arctic Sun Stat Temperature Management System, are identical to the predicate device.

Technological Comparison to Predicate Device

The subject Arctic Sun Stat Temperature Management System has the following similarities to the predicate device (K161602 for Arctic Sun Temperature Management System):

- Identical intended use
- Identical indications for use
- Identical target population
- Equivalent operating principle
- Identical fundamental scientific technology
- Similar cleaning process
- Similar packaging materials and configuration

The subject Arctic Sun Stat Temperature Management System has the following differences when compared to the predicate device:

- Software modifications
  1. Updated the graphical user interface (GUI)
  2. Pad size selection available during therapy initiation
  3. Added 2nd option for the heat transfer indicator (Work to Cool)
  4. Added optional upper and lower patient temperature limits (Monitor Mode)
  5. Added alarm for upper and lower patient temperature limits (Monitor Mode)
  6. Added another data output method (Wi-Fi)
  7. Updated operating system (OS) and code architecture
  8. Removed the option for the user to upload a jpg
  9. Updated the default upper limit for water temperature control
  10. Updated the alarm naming and prioritization

- Component changes
  11. Industrial design was changed to differentiate next generation product
  12. Added Wi-Fi card
  13. Changed the control panel
  14. Updated packaging based on industrial design change

- Labeling changes
  15. Clarifications in the instructions for use
  16. Added warning for additional information on electromagnetic interference
  17. Added warning for additional information on protection against the effects of discharge of cardiac defibrillators
  18. Added caution for heat transfer indicator (Work to Cool)
  19. Updated caution for manual control
  20. Added complication statement for targeted temperature management

- Other changes made to the predicate device since the last clearance
  21. Added warning against use in the operating room
  22. Clarified the type of circulating fluid to be used in the device
  23. Added information regarding preventative maintenance

Performance Data

To demonstrate substantial equivalence of the subject device to the predicate device, the technological characteristics and performance criteria of the subject device were evaluated. No clinical testing was required to evaluate the changes for substantial equivalence. Using internal risks assessment procedures as well as FDA Guidance Documents on software, radio frequency wireless technology in medical devices, and reprocessing, the following tests were performed on the subject device.

Summary of Performance Testing Used to Establish Substantial Equivalence

		Proposed Change Type		
		Software	**Hardware**	**Labeling**
FDA's Criteria for Well-Established Methods	**FDA recognized consensus standards**	• ES 60601-1 • IEC 60601-1-8 • IEC 62304 • IEC 80601-2-35 • IEC 62366-1	• ES 60601-1 • IEC 60601-1-2	• Medical Electrical Equipment (MEE) standards
	FDA guidance documents	• Radio frequency • Cybersecurity • Software	• Radio frequency • Reprocessing	
	Medivance, Inc.'s methods used in previous submissions	• Graphical user interface (GUI) • Artificial patient • Regression • Alarm conditions	• Dimensional analysis • Chiller response time • Artificial patient • Warming capacity • Water temp stability • Packaging integrity • Corrosion resistance	• Labeling verification

The performance tests used to evaluate the proposed changes are based on methods previously provided to FDA in a previous 510(k) submission for the predicate device (K161602), as well as FDA recognized consensus standards and FDA Guidance documents. The testing methods from previous 510(k) submissions include artificial patient testing, software and graphical user interface testing, mechanical testing, and electrical testing. The FDA recognized consensus standards for Medical Electrical Equipment (MEE) detail test methods and these were executed on the subject device. A summary of these tests is provided along with references to the specific standards and previous submission. An explanation of any differences in those methods is provided, when applicable. The predicate device was most recently cleared in K161602. No clinical data or testing was required to evaluate the proposed device modifications that are the subject of this submission. The results from these tests demonstrate that the technological characteristics and performance criteria of the Arctic Sun Stat Temperature Management System are substantially equivalent to the predicate device and performs in a manner equivalent to devices currently on the market for the same intended use.

Conclusions

The subject device, Arctic Sun Stat Temperature Management System (including the Arctic Sun Stat Control Module and associated accessories), is substantially equivalent to the predicate device, the Arctic Sun Temperature Management System.