April 30, 2025

Medivance, Inc.
Lauren Valdes
Regulatory Affairs Manager
321 South Taylor Avenue
Suite 200
Louisville, Colorado 80027

Re: K243942
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: December 20, 2024
Received: April 10, 2025

Dear Lauren Valdes:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Nicole M. Gillette -S

Nicole Gillette
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243942

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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: Lauren Valdes
Regulatory Affairs Manager
Telephone: 678-231-1627
E-mail: Lauren.Valdes@bd.com

Date of Submission: December 20, 2024

Subject Device Name: Arctic Sun™ Stat Temperature Management System

Subject Device

Device Trade Names:	Arctic Sun™ Stat Temperature Management System
Common Name:	Patient Temperature Management System
Regulation Name:	Thermal Regulating System
Regulation Number:	21 CFR 870.5900
Product Code:	DWJ
Regulatory Class:	II
Classification Panel:	Cardiovascular
Prior Correspondence:	None

Predicate Device

510(k) Number:	K200225
Device Trade Name:	Arctic Sun™ Stat Temperature Management System
Common Name:	Patient Temperature Management System
Regulation Name:	Thermal Regulating System
Regulation Number:	21 CFR 870.5900
Product Code:	DWJ
Regulatory Class:	II
Classification Panel:	Cardiovascular

Device Description

The Arctic Sun™ Stat Temperature Management System is a non-invasive, thermal regulating 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 system consists of a console, non-sterile single patient use ArcticGel™ Pads, and associated accessories.

The Arctic Sun™ Stat Temperature Management System 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 Yellow Springs Instrument (YSI) 400 series compatible patient temperature probe connected to the console 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 console 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.

Substantial Equivalence

Indications for Use

The Arctic Sun™ Stat Temperature Management System is a thermal regulating system, indicated for monitoring and controlling patient temperature in adult and pediatric patients of all ages. The Arctic Sun™ Stat Temperature Management System and the predicate device have the same indications for use.

Intended Use

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 Arctic Sun™ Stat Temperature Management System and the predicate device have the same intended use.

Technological Comparison to Predicate Device

The Arctic Sun™ Stat Temperature Management System is the same as the predicate device in the following manner:

- Intended Use
- Indications for Use
- Target user and patient population
- Control and monitoring processes
- Principle of operation
- Control algorithm
- Patient temperature control range
- Hypothermia and Normothermia therapy modes
- Fundamental technology to monitor and control patient temperature

The subject Arctic Sun™ Stat Temperature Management System has the following modifications for one of the water temperature alarms when compared to the predicate device:

- Software modifications for alarm conditions, prioritization, and user explanatory text
- Labeling modifications to reflect changes made to alarm prioritization and explanatory text

The subject Arctic Sun™ Stat Temperature Management System has the following other minor modifications when compared to the predicate device:

- Software modifications
  - New notification banner when Manual Mode is employed
  - WPA2 Enterprise and hidden Wi-Fi network support
  - Software anomaly corrections
- Other changes made to the predicate device since the last clearance
  - Labeling (temperature simulator caution moved to warnings section, clarifications for readability)
  - Software modifications to improve Wi-Fi data output clarity, branding, and anomaly corrections
  - New/modified components

Performance Data

Performance testing was developed and executed according to internal design control and risk assessment procedures, software FDA Guidance documents, and applicable FDA recognized consensus standards. Software validation of the Arctic Sun™ Stat Temperature Management System was performed to verify all new system and software requirements, the result of which confirmed the function of the device modifications. No clinical testing was required to evaluate substantial equivalence. The following table lists the relevant nonclinical tests performed on the Arctic Sun™ Stat Temperature Management System.

Arctic Sun™ Stat Temperature Management System – Nonclinical Tests Performed
System mechanical verification
System electrical safety
Electrical reliability
Software verification
Control accuracy and precision
Electromagnetic compatibility
Radio frequency
Alarm functionality
Artificial patient testing
Cybersecurity
Packaging integrity
Human factors and validation

The results from this testing demonstrate that the technological characteristics and performance criteria of the subject device 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 purpose of this 510(k) notification is to obtain market clearance for safety enhancements made to the software of the Arctic Sun Stat console and related labeling. These enhancements maintain the substantial equivalence of the device to the legally marketed predicate device. The Arctic Sun™ Stat Temperature Management System, as designed and manufactured, does not raise new questions regarding safety and effectiveness as compared to the predicate device.