



October 24, 2025

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

Re: K251974

Trade/Device Name: Arctic Sun Temperature Management System (Model 5000)  
Regulation Number: 21 CFR 870.5900  
Regulation Name: Thermal Regulating System  
Regulatory Class: Class II  
Product Code: DWJ  
Dated: September 3, 2025  
Received: September 3, 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Kathleen M.  
Grunder -S**

for 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

## Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K251974

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Please provide the device trade name(s).

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Arctic Sun Temperature Management System (Model 5000)

Please provide your Indications for Use below.

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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.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)  
 Over-The-Counter Use (21 CFR 801 Subpart C)

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**510(k) Summary – K251974**

**Arctic Sun™ Temperature Management System Model 5000**

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

**Contact Person:** Lauren Valdes  
Sr Regulatory Affairs Manager  
Telephone: 678-231-1627  
E-mail: [Lauren.Valdes@bd.com](mailto:Lauren.Valdes@bd.com)

**Date of Submission:** September 3, 2025

**Subject Device Name:** Arctic Sun™ Temperature Management System Model 5000

**Subject Device**

Device Trade Names: Arctic Sun™ Temperature Management System Model 5000  
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: K161602  
Device Trade Name: Arctic Sun™ Temperature Management System Model 5000  
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

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## Device Description

The Arctic Sun™ Temperature Management System Model 5000 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™ Temperature Management System Model 5000 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™ Model 5000 console has the option to provide secure data output of device monitoring values; there is no patient-identifiable information. The data output functions, which are USB and RS-232, 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™ 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™ Temperature Management System Model 5000 and the predicate device have the same indications for use.

### Intended Use

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 Model 5000 and the predicate device have the same intended use.

## Technological Comparison to Predicate Device

The Arctic Sun™ Temperature Management System Model 5000 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™ Temperature Management System Model 5000 has the following modifications for one of the water temperature alarms when compared to the predicate device:

- Software modifications for alarm conditions and prioritization
- Labeling modifications to reflect changes made to alarm prioritization and clarify service life

Additionally, the subject Arctic Sun™ Temperature Management System Model 5000 has labeling modifications to provide clarification, component changes, and minor software and packaging changes made to the predicate device since the last clearance.

### 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™ Temperature Management System Model 5000 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 performance testing used to establish substantial equivalence of the Arctic Sun™ Temperature Management System Model 5000.

<b>Arctic Sun™ Temperature Management System Model 5000 – Nonclinical Tests Performed</b>
Software verification
Control accuracy and precision
Alarm functionality
Artificial patient testing
Cybersecurity

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™ Temperature Management System Model 5000, as designed and manufactured, does not raise new questions regarding safety and effectiveness as compared to the predicate device.