October 30, 2026

Medivance, Inc.
Monica Williams
Regulatory Affairs Specialist II
321 S. Taylor Ave.
Suite 200
Louisville, Colorado 80033

Re: K263587
Trade/Device Name: Arctic Sun™ Neonatal ArcticGel™ Pad
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: September 30, 2026
Received: September 30, 2026

Dear Monica Williams:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@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

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.	K263587

Please provide the device trade name(s).

Arctic Sun™ Neonatal ArcticGel™ Pad

Please provide your Indications for Use below.

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.

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

510(k) Summary

Arctic Sun™ Neonatal ArcticGel™ Pad

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

Contact Person: Monica Williams
Regulatory Affairs Specialist II
Telephone: 720-340-1187
E-mail: monica.williams@bd.com

Date of Submission: September 29, 2026

Subject Device Name: Arctic Sun™ Neonatal ArcticGel™ Pad

Subject Devices

Device Trade Names:	Arctic Sun™ Neonatal ArcticGel™ Pad
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

Predicate Devices

510(k) Number:	K142702
Device Trade Name:	Arctic Sun™ Temperature Management System (including the ArcticGel™ pads)
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™ 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™ Neonatal ArcticGel™ Pads are intended for use with the Arctic Sun™ Temperature Management System, to provide energy (heat) transfer between the patient and the temperature-controlled water circulating through the Neonatal ArcticGel™ Pads in order to provide targeted temperature management.

Each pad has a connection with an inlet and outlet that attaches to a fluid delivery line that is connected to the Arctic Sun™ control module. Only one Neonatal Pad is connected to the console at one time. The pads allow water to disperse and flow within internal pathways to provide even, efficient heat transfer between the skin and water. The subject Neonatal ArcticGel™ Pad utilizes a patient contacting fabric material and can be secured to the patient using Velcro straps.

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.

Comparison of Technological Characteristics With the Predicate Device

The technological characteristics of the Arctic Sun™ Neonatal ArcticGel™ Pad are substantially equivalent and do not alter the safety and effectiveness when compared to the predicate, Neonatal ArcticGel™ Pad of the Arctic Sun™ Temperature Management System (including the ArcticGel™ pads). The subject device has the same intended use and indications for use to the predicate device.

The Arctic Sun™ Neonatal ArcticGel™ Pad is the same as the predicate device in the following ways:

- Intended Use
- Indications for Use
- Target user and patient population
- Fundamental scientific technology
- Materials
- System features and functions

The following difference exists between the subject and predicate devices:

- Dimensional design modification to the foam layer dimples

Other than this dimensional design modification, there are no other design or labeling changes to the predicate device (K142702) clearance that would result in a new 510(k).

Table 1. below provides a comparison of the technological characteristics between the subject and predicate device. This comparison is abbreviated to include only the intended use, indications for use, and the specific characteristics changing which are subject to this Special 510(k) submission.

Table 1. Technological Characteristics Comparison

Design / Technological Characteristic	**Subject Device: Arctic Sun™ Neonatal ArcticGel™ Pad**	**Predicate Device: Neonatal ArcticGel™ Pad of Arctic Sun™ Temperature Management System (including the ArcticGel™ pads)**
FDA Clearance Number	Subject of this submission	K142702
Classification Regulation	21 CFR § 870.5900 – Thermal regulating system	21 CFR § 870.5900 – Thermal regulating system
FDA Product Code	DWJ	DWJ
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 is a thermal regulating system, indicated for monitoring and controlling patient temperature in adult and pediatric patients of all ages.
Thermoformed Pad Layer Dimple Height	Proprietary dimension increased by 33%	Proprietary dimension

Performance Data

Performance testing was developed and executed according to internal design control and risk assessment procedures, FDA Guidance documents, and applicable FDA recognized consensus standards. The following list consists of the nonclinical tests performed on the subject device for an evaluation of substantial equivalence of the subject devices to the predicate devices: heat transfer and flow performance testing.

The results from this testing demonstrate that the technological characteristics and performance criteria of the Arctic Sun™ Neonatal ArcticGel™ Pad are substantially equivalent to the predicate device.

Conclusion

Based on substantially equivalent indications for use, technological characteristics, and safety and performance testing, the subject Arctic Sun™ Neonatal ArcticGel™ Pad device has been determined to be substantially equivalent and does not raise new questions regarding safety and effectiveness when compared to the legally marketed predicate Neonatal ArcticGel™ Pad of the Arctic Sun™ Temperature Management System (including ArcticGel™ pads) device.