April 16, 2026

Xodus Medical, Inc.
% Prithul Bom
President and CEO
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

Re: K260903
Trade/Device Name: Hot Pink Pad Warming System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: February 3, 2026
Received: March 18, 2026

Dear Prithul Bom:

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 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 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.

510(k) Number *(if known)*
K260903

Device Name
Hot Pink Pad Warming System

Indications for Use *(Describe)*
The Hot Pink Pad Warming System is a non-sterile, electrically conductive patient warming system with adjustable temperature in a predefined range.

The Hot Pink Pad Warming System is to be used during surgical procedures to assist in patient temperature management and prevent inadvertent hypothermia.

The Hot Pink Pad Warming System is intended for use in hospitals and surgery centers.

The Hot Pink Pad Warming System's patient population includes adult and pediatric patients, but excludes neonatal patients.

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.

510(k) Summary K260903

510(k) Owner: Xodus Medical, Inc.
Westmoreland Business & Research Park
702 Prominence Drive
New Kensington, PA 15068
Phone: 724-337-5500
Fax: 724-337-1131
Contact: Paul Lloyd (Chief Technical Officer & EVP Global QA/RA)

Establishment Registration Number: 2530138

Date Prepared: April 16, 2026

1. Device Information

1.1. Trade/Device Name: Hot Pink Pad Warming System
1.2. Common Name: Thermal Regulating System
1.3. Classification Name: System, Thermal Regulating
1.4. Regulation Number: 21 CFR 870.5900
1.5. Product Code: DWJ
1.6. Regulatory Class: II

2. Legally Marketed Devices to which Xodus Medical claims Substantial Equivalence

2.1. Device Name: ASTOPAD Patient Warming System
2.2. Common Name: Thermal Regulating System
2.3. 510(k) Number: K202197
2.4. 510(k) Owner: Stihler Electronic GmbH
Julius-Hoelder-Strasse 36
Stuttgart, DE 70597
2.5. Classification Name: System, Thermal Regulation
2.6. Regulation Number: 21 CFR 870.5900
2.7. Product Code: DWJ
2.8. Regulatory Class: II

3. Device Description

The Hot Pink Pad Warming System is an active warming system that is designed to assist in patient temperature management and prevent inadvertent hypothermia for use in surgical procedures. Included with the system is a reusable controller, reusable connecting signal cable, reusable AC power cord, and a single use Hot Pink Pad (warming pad).

The controller is to be secured to an IV pole or similar. The controller has the functionality to set and regulate the desired temperature for the heating function of the system using the front panel display. The set-temperature of the connected warming pad can be selected between a range from 36.0°C to 40.0°C in 0.5°C increments. The controller also detects faults and provides alarming via

an audible source and the controller LCD display. The controller is a reusable device that remains in the OR when not being used.

The controller has one fifteen-foot reusable signal cable that connects to the single use warming pad.

The warming pad of the Hot Pink Pad Warming System is a single use device. It uses Xodus Medical's Pink Pad that provides patient protection and safety during surgical procedures when positioning a patient on the OR table.

The Hot Pink Pad Warming System is not intended to regulate the patient's body temperature and does not display associated patient temperature data. The display indicates current temperature of the warming pad's heated core. Temperature regulation of the Hot Pink Pad Warming System's warming function is measured using several integrated sensors located on the pad.

The warming pad is a single use device and must be discarded following use in accordance with hospital policy.

Patient safety of the Hot Pink Pad Warming System is ensured by the following measures for each output:

- Multiple sensors on the warming pad for software driven temperature regulation
- Independent sensor monitoring with one dedicated mechanical sensor for overtemperature detection
- Visual and audible alarm signals

4. Indication for Use

The Hot Pink Pad Warming System is a non-sterile, electrically conductive Patient Warming System with adjustable temperature in a pre-defined range. The Hot Pink Pad Warming System is to be used during surgical procedures to assist in patient temperature management and prevent inadvertent hypothermia.

The Hot Pink Pad Warming System is intended for use in hospitals and surgery centers.

The Hot Pink Pad Warming System's patient population includes adult and pediatric patients, but excludes neonatal patients.

5. Software Overview

The Hot Pink Pad controller includes a software application that provides user interface and system control functions.

The software application provides an intuitive user interface for the operator to choose a desired temperature setpoint for the Hot Pink Pad. The user interacts with the software via three buttons on the controller: Temperature Up, Temperature Down, and Alarm Silence. The software application also provides visible and audible alerts to the user for various alarm conditions that can occur.

During use, the software monitors the temperature of the Hot Pink Pad and controls the application of energy to the pad to regulate the temperature to the desired setpoint. A redundant hardware-only overtemperature circuit informs the software of any unsafe temperature condition.

6. Description of Safety and Substantial Equivalence

The Xodus Medical Hot Pink Pad Warming System and the predicate device, ASTOPAD Patient Warming System are both non-invasive patient warming systems intended to assist in maintaining patient temperature management and prevent inadvertent hypothermia during surgical procedures. The Xodus Medical Hot Pink Pad Warming System and ASTOPAD Patient Warming System are based on the same technological characteristics shown in the table below.

Substantial Equivalence Comparison of Technological Characteristics

Feature / Characteristic	**Predicate Device: ASTOPAD® Patient Warming System (K202197)**	**Subject Device: Hot Pink Pad Warming System**	**Substantial Equivalence Justification**
Regulation Number	21 CFR 870.5900	21 CFR 870.5900	Identical regulation
Product Code	DWJ	DWJ	Identical product code
Device Classification	Class II	Class II	Identical classification
Intended Use	To prevent or treat hypothermia and to provide warmth to patients.	To assist in patient temperature management and prevent inadvertent hypothermia during surgical procedures	Minor variations in phrasing and specificity that do not represent a change in the fundamental intended use.
Use Environment	ORs, hospitals, surgical centers	ORs, hospitals, surgical centers	Identical
Patient Population	Adult and pediatric (excludes neonatal)	Adult and pediatric (excludes neonatal)	Identical

Feature / Characteristic	Predicate Device: ASTOPAD® Patient Warming System (K202197)	Subject Device: Hot Pink Pad Warming System	Substantial Equivalence Justification
Heating Mechanism	Resistive conductive heating via reusable pad	Resistive conductive heating via single-use pad	Minor difference; does not affect safety/effectiveness
Temperature Range	32.0°C to 39.0°C (0.5°C increments)	36.0°C to 40.0°C (0.5°C increments)	Similar, performance test will be conducted.
Controller Outputs	Two independent outputs	One output	Acceptable difference: risk analysis will support safety
Patient Temp Monitoring	Not provided	Not provided	Identical
Setpoint Control	Via control unit display panel	Via control unit display panel	Identical
Visual/Audible Alarms	Yes	Yes	Identical
Over-Temperature Protection	Yes, automatic shutoff and alarm	Yes, automatic shutoff and alarm	Equivalent protection functionality
Applied Part Material	Reusable fabric covered foam pad	Single-use foam pad	Lower risk due to single use disposable with no incidence of cross contamination or degradation. Difference mitigated by safety testing.
Power Supply	Mains; optional battery operation	Mains only	Acceptable difference; does not impact core function
Temperature Sensors	Multiple integrated sensors per blanket	Multiple integrated sensors per pad	Identical implementation strategy
Control Unit Mounting	Universal mounting clamp	Universal mounting clamp	Identical

7. Performance Data

7.1. Electrical Safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Hot Pink Pad Warming System, consisting of the control unit and an applied part. Testing shows the system complies with the applicable requirements of IEC 60601-1, IEC 60601-1-6, IEC 60601-1-8 and IEC 60601-2-35 standards for safety and IEC 60601-1-2 standard for EMC.

7.2. Software Verification and Validation Testing

Software verification and validation testing were conducted on the Hot Pink Pad Warming System, and documentation was provided in accordance with IEC 62304 and IEC 60601-1 PEMS.

7.3. Mechanical testing

Mechanical testing was conducted on the Hot Pink Pad Warming System within the testing of the standards IEC 60601-1 and IEC 80601-2-35.

Testing shows the system complies with the applicable mechanical requirements of the standards.

7.4. Thermal testing

Thermal testing was conducted on the Hot Pink Pad Warming System within the testing of the standards IEC 60601-1 and IEC 60601-2-35.

Testing shows the system complies with the applicable thermal requirements of the standards.

7.5. Human Factors Validation Testing

Human factors validation testing for the Hot Pink Pad Warming System was conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Applying Human Factors and Usability Engineering to Medical Devices" and in accordance with the IEC 60601-1-6 and IEC 62366-1.

The Hot Pink Pad Warming System has been found to be safe and effective for the intended users, use and use environments.

7.6. Reprocessing Testing

The Hot Pink Pad controller, signal cable, and AC power cord are classified as a reusable medical device which requires cleaning and disinfecting after each use.

Required cleaning and disinfection validation testing were conducted on the control unit and on the reusable cabling.

The Hot Pink Pad Warming System meets the applicable cleaning & disinfecting performance criteria, when cleaned and disinfected as labeled.

7.7. **Animal Study** Not required

7.8. **Clinical Study** Not required

7.9. **Biocompatibility Testing**

Biocompatibility endpoint testing is not required.

8. Conclusion

The design, characteristics, and performance of the Hot Pink Pad Warming System substantiate that the device works as intended, to be used during surgical procedures to assist in patient temperature management and prevent inadvertent hypothermia. The Xodus Medical Hot Pink Pad Warming System is considered substantially equivalent to its predicate device, ASTOPAD Patient Warming System.