January 21, 2020

DeRoyal Industries, Inc.
Sarah Bennett
Senior Regulatory Affairs Specialist
200 DeBusk Lane
Powell, Tennessee 37849

Re: K191425
Trade/Device Name: Hydro-Temp® Neonatal Skin Temperature Probe Cover
Regulation Number: 21 CFR 880.5130
Regulation Name: Infant Radiant Warmer
Regulatory Class: Class II
Product Code: FMT
Dated: December 20, 2019
Received: December 23, 2019

Dear Sarah Bennett:

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,

for Geeta Pamidimukkala
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology 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)*
K191425

Device Name
HYDRO-TEMP® Neonatal Skin Temperature Probe Cover

Indications for Use *(Describe)*
The DeRoyal HYDRO-TEMP® Neonatal Skin Temperature Probe Covers are used to adhere the thermistor of the temperature probe to the patient and insulate the thermistor from ambient room temperature ensuring correct temperature readings.

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

Date prepared:	January 16, 2020
510(k) Owner:	DeRoyal Industries, Inc. 200 DeBusk Lane Powell, TN 37849 Owner/Operator #1044833
510(k) Contact:	Sarah Bennett Senior Regulatory Affairs Specialist P: 865-362-6112 sabennett@deroyal.com
Contract Manufacturer:	DeRoyal Industries, Inc. 185 Richardson Way Maynardville, TN 37849 FDA Establishment # 1034876
Trade Name:	HYDRO-TEMP® Neonatal Skin Temperature Probe Cover
Common Name:	Skin Temperature Probe Cover
Classification Name:	Warmer, Infant Radiant
Device Product Code:	FMT
Regulatory Class:	Class II
Regulation Name:	21 CFR 880.5130
Classification Panel:	General Hospital
Predicate Devices:	HYDRO-TEMP® NICU and Skin Surface Temperature Sensor

Device Description
The HYDRO-TEMP® Neonatal Skin Temperature Probe Cover is an accessory to be used with DeRoyal-branded NICU neonatal skin temperature probes used with an infant radiant warmer. They have not been evaluated for use with other manufacturer's

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products. It is an adhesive pad used to affix a temperature sensor to a neonate's skin to monitor the skin surface temperature. The cover also insulates the temperature sensor from ambient room temperature to ensure temperature readings are accurate.

There are two configurations of the probe cover. Both of these configurations contain a release liner, a patient-contacting hydrogel adhesive, and a metallized polyester backing. One configuration contains an additional foam material that is placed in between the hydrogel adhesive and metallic backing. The device is non-sterile and can be packaged on its own in a foil pouch or in a resealable plastic bag with a temperature probe.

Indications for Use:
The DeRoyal HYDRO-TEMP® Neonatal Skin Temperature Probe Covers are used to adhere the thermistor of the temperature probe to the patient and insulate the thermistor from ambient room temperature ensuring correct temperature readings.

Differences to Predicate Device:
The subject device has greater adhesive bond to the predicate device. This was demonstrated through peel strength testing between both devices. The Indications for Use statement for the subject device is specifically for the probe cover whereas the predicate device included the temperature sensor probe and the probe cover for monitoring temperature. The differences in thickness do not impact the safety or effectiveness.

Summary of Technological Characteristics

Characteristic	**HYDRO-TEMP® Neonatal Skin Temperature Probe Cover**	**HYDRO-TEMP® NICU and Skin Surface Temperature Sensor Probe (K925006)**
Prescription Only	Yes	Yes
Use Environment	NICU	NICU
Design	A pad consisting of a release liner, non-sensitizing hydrogel adhesive that contacts the patient's skin, and metalized film backing. One configuration also contains a polyethylene foam that is placed in between the gel and film.	The device is a disposable skin surface temperature probe. The device consists of wire sets and a pad. The pad holds the sensing device against the skin. It is adhesive lined or hydrogel lined foam. The pad is composed of materials which will insulate the sensing elemnt from the ambient temperature and adhere the element to the skin.
Materials	Release liner: Polyester film	Release liner: Polyester film

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	Patient adhesive: Hydrogel Foam: Polyethylene foam Backing: Metallic polyester film	Patient adhesive: Hydrogel Foam: Polyethylene foam Backing: Metallic polyester film
Adhesive	Hydrogel	Hydrogel
Sterility	Non-Sterile	Non-Sterile
Biocompatibility	ISO 10993-1 compliant	ISO 10993-1 compliant
Average peel force per ASTM D903-98	4.42N	4.28N
Average force required to remove cover from surface	10.1N	9.1N

Summary of Performance Tests

Mechanical testing was performed to evaluate the adhesive performance of the proposed device compared to the predicate per ASTM D903-98 (Reapproved 2017) – Standard Test Methods for Peel or Stripping Strength of Adhesive Bonds. The results of this testing demonstrate the proposed device has a greater adhesive strength than the predicate. A pull test was performed to evaluate the adhesive performance of the proposed device to the predicate. This was performed to an internal standard. Insulation testing demonstrated that the new material did not result in a temperature difference from the predicate device. Accuracy testing was performed to IEC 60601-2-21 demonstrating the tolerance range of temperature readings when the probe cover was used. The following biocompatibility tests also were performed in accordance with ISO 10993 and FDA guidance: cytotoxicity, sensitization, and irritation. These results show that the proposed device is biologically safe for its intended use.

Conclusion

The HYDRO-TEMP® Neonatal Skin Temperature Probe Cover is substantially equivalent to the predicate device, HYDRO-TEMP® NICU and Skin Surface Temperature Sensor (K925006). The tests performed demonstrate the device is substantially eqivalent to the predicate device. The proposed device is similar to the predicate but with a modified hydrogel material to improve the adhesive strength, which is supported by performance testing.