April 2, 2020

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

Re: K200319
Trade/Device Name: HYDRO-TEMP Neonatal Skin Surface Temperature Sensor, HYDRO-TEMP Neonatal Skin Surface Temperature Sensor with Interface Cable
Regulation Number: 21 CFR 880.5130
Regulation Name: Infant Radiant Warmer
Regulatory Class: Class II
Product Code: FMT
Dated: February 5, 2020
Received: February 7, 2020

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 Tina Kiang, Ph.D.
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)*
K200319

Device Name
HYDRO-TEMP Neonatal Skin Surface Temperature Sensor

Indications for Use *(Describe)*
The HYDRO-TEMP Neonatal Skin Surface Temperature Sensor is a non-sterile device intended for connection to an infant radiant warmer to monitor the neonatal patient's skin surface temperature.

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:	February 5, 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 F: 865-362-3741 sabennett@deroyal.com
Contract Manufacturer:	DeRoyal Cientifica de Latinoamerica S.R.L. Global Park Box 180-3006, 602 Parkway La Aurora, Heredia Heredia, Costa Rica 146 DeRoyal Industries, Inc. 185 Richardson Way Maynardville, TN 37807
Trade Name:	HYDRO-TEMP Neonatal Skin Surface Temperature Sensor HYDRO-TEMP Neonatal Skin Surface Temperature Sensor with Interface Cable
Common Name:	Skin Surface Temperature Sensor
Classification Name:	Warmer, Infant Radiant
Device Product Code:	FMT
Regulatory Class:	Class II
Regulation Number:	21 CFR 880.5130
Classification Panel:	General Hospital

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Predicate Devices: HYDRO-TEMP NICU and Skin Surface Temperature Sensor [K925006]

Device Description
The HYDRO-TEMP Neonatal Skin Surface Temperature Sensor consists of a probe used to monitor a neonate's skin surface temperature used as an accessory while the patient is on an infant radiant warmer. The probe is a wire set with a thermistor chip at the distal end that passively modifies the electrical current traveling through the device. A colored connector at the proximal end of the wire set interfaces with the warming bed or a cable that interfaces with the bed. The probe is packaged with an adhesive pad used to affix the sensor to the patient's skin surface.

The device is non-sterile and individually packaged in a resealable plastic bag. The probe covers that are packaged with the probe are cleared under K191425. The probes are compatible with the following warming beds: Datex-Ohmeda (Ohmeda, Care Plus, and IWS brands), Draeger (Babytherm, Isolette, Babyleo, Caleo, Resuscitaire, ICS, and Globe-Trotter brands), Atom (Transcapsule, Infa Warmer, INCU 1, and Sunflower brands), and GE (Giraffe and Panda brands).

Indications for Use
The HYDRO-TEMP Neonatal Skin Surface Temperature Sensor is a non-sterile device intended for connection to an infant radiant warmer to monitor the neonatal patient's skin surface temperature.

Differences to Predicate Device
The encapsulation method of the subject device is different that the predicate device. The predicate device, the current encapsulation method utilizes a molded plastic cap that is filled with epoxy glue, and the thermistor is inserted into this cap. In the subject device, these materials would be replaced with a UV-cured adhesive. The thermistor is dipped into the adhesive and cured under UV light. This is the only component change in the device. The thermistor cap directly contacts the patient's intact skin.

Summary of Technological Characteristics

Characteristic	**HYDRO-TEMP Neonatal Skin Surface Temperature Sensor**	**HYDRO-TEMP NICU and Skin Surface Temperature Sensor Probe (K925006)**

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Prescription Only	Yes	Yes
Use Environment	NICU	NICU
Design	A wire set packaged with an adhesive pad. The wire set has a thermistor chip at the distal end and a colored connector at the proximal end.	A wire set packaged with an adhesive pad. The wire set has a thermistor chip at the distal end and a colored connector at the proximal end.
Materials	Probe Cover – Adhesive pad with polyester film backing and release liner Wire – Copper with PVC insulation Thermistor – Ceramic Connector – Plastic-molded metal connector Strain Relief – PVC Cap – UV-curing Adhesive	Probe Cover – Adhesive pad with polyester film backing and release liner Wire – Copper with PVC insulation Thermistor – Ceramic Connector – Plastic-molded metal connector Strain Relief – PVC Cap – PVC and epoxy glue
Accuracy	±0.2°C	±0.2°C
Sterility	Non-Sterile	Non-Sterile
Biocompatibility	ISO 10993-1 compliant	ISO 10993-1 compliant
Shelf life	1 year (intent to extend to 5 years once testing completed)	3 years

Summary of Performance Tests
The proposed device has been tested and/or evaluated according to the following standards as applicable: ISO 10993-1, IEC 60601-2-21, ISO 80601-2-56, IEC 60601-1, IEC 60601-1-2.

The following biocompatibility tests were performed on the final, finished proposed device in accordance with ISO 10993 and FDA guidance: cytotoxicity, sensitization, and irritation. These results show the proposed device is biologically safe for its intended use.

Accuracy testing was performed to IEC 60601-2-21 demonstrating the tolerance range of temperature readings with the proposed change. Additionally, a time response test in accordance with ISO 80601-2-56 also was performed. The results of this testing demonstrate proposed modification to the thermistor encapsulation does not impact the device's performance of its intended use. Evaluation and testing according to IEC 60601-1 and IEC 60601-1-2 also was performed to ensure the change to the thermistor encapsulation did not affect the electrical safety of the device.

All testing was performed on final, finished product manufactured with the proposed modification. The test results met the requirements of the aforementioned standards and demonstrate that

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the proposed modification does not impact the safet or efficacy of the device.

Conclusion

The results of performance testing demonstrate the HYDRO-TEMP Neonatal Skin Surface Temperature Sensor is substantially equivalent to the predicate device. The difference between the predicate device and subject device is change to the thermistor encapsulation method and all other features are the same.