December 23, 2020

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

Re: K200631
Trade/Device Name: DeRoyal Temperature Monitoring Probe
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: November 23, 2020
Received: November 24, 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,

CAPT Alan M. Stevens
Acting 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: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200631

Device Name
DeRoyal Temperature Monitoring Probe

Indications for Use *(Describe)*
The DeRoyal Temperature Monitoring Probe is used for routine monitoring of the patient's core body or skin surface temperature.

The probe is offered in the following three configurations:
- General Purpose Temperature Probe for routine monitoring of the core body temperature in adult and pediatric patients by insertion into the nasopharyngeal, esophageal, or rectal cavities.
- Adult Skin Temperature Sensor for routine monitoring of skin temperature by application of the probe's adhesive cover to an adult patient's skin surface.
- Tympanic Temperature Probe for routine monitoring of the core body temperature in adult and pediatric patients by insertion of the ear piece into the aural canal.

The device is single use and for use by licensed healthcare practitioners only. The probes are designed to interface with DeRoyal-branded cables for connection with YSI 400 or 700 series compatible monitors, including the following patient monitors and equivalent models: Mindray Passport, Philips IntelliVue, Siemens/Draeger Infinity, and GE Datex-Ohmeda brands.

Type of Use *(Select one or both, as applicable)*
X Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date prepared:	November 23, 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:	DeRoyal Temperature Monitoring Probe
Common Name:	Temperature Monitoring Probe
Classification Name:	Thermometer, Electronic, Clinical
Device Product Code:	FLL
Regulatory Class:	Class II
Classification Panel:	General Hospital
Regulation Number:	21 CFR 880.2910
Predicate Devices:	Exac-Temp & Clini-Temp Probe w/ Temperature Sensor [K925791] – Primary Predicate Exac-Temp & Clini-Temp Tympanic Probe [K925792]

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	Skin Surface Temperature Sensor [K925006]
Reference Devices:	Skin Sensor Probe, General Purpose Probe, Tympanic Probe [K101244]
	Esophageal/Rectal Temperature Probe [K140134]
	Disposable Temperature Probe [K181967]

Device Description
The DeRoyal Temperature Monitoring Probe is used for routine patient temperature monitoring. Each probe is single use and contains a wire set with a blue connector at the proximal end and a thermistor chip at the distal end. The thermistor passively modifies the electrical current traveling through the probe. The connector interfaces with a cable that is connected to an independent temperature monitor used to display the temperature readings.

There are three probe configurations included in this submission:

1. An **adult skin temperature sensor** that consists of the wire set with an adhesive probe cover that is applied to the patient's intact skin for monitoring of skin surface temperature.
2. A **tympanic temperature probe** that consists of the wire set with a foam ear plug that is inserted into the aural canal for monitoring of core body temperature.
3. A **general purpose temperature probe** that consists of the wire set enclosed in a tube that may be inserted into the esophageal, rectal, or nasopharyngeal cavities for monitoring of core body temperature.

All probes are individually packaged. The tympanic configuration is non-sterile. The other two configurations are sold sterile. The probes are designed to interface with DeRoyal-branded cables for connection with YSI 400 or 700 series compatible monitors, including the following patient monitors and equivalent models: Mindray Passport, Philips IntelliVue, Siemens/Draeger Infinity, and GE Datex-Ohmeda brands.

Intended Use
The DeRoyal Temperature Monitoring Probe is used for routine monitoring of the patient's core body or skin surface temperature.

Summary of Technological Characteristics

Characteristic	Configuration	Proposed Device	Predicate 510(k)	Predicate Device	Differences
Indications for Use	General Purpose	The DeRoyal Temperature Monitoring Probe is used for routine monitoring of the patient's core body or skin surface temperature. The probe is offered in the following three configurations: - General Purpose Temperature Probe for routine monitoring of the core body temperature in adult and pediatric patients by insertion into the nasopharyngeal, esophageal, or rectal cavities; - Adult Skin Temperature sensor for routine monitoring of skin temperature by application of the probe's adhesive cover to an adult patient's skin surface. - Tympanic Temperature Probe for routine monitoring of the core body temperature in adult and pediatric patients	K925791 – Exac-Temp & Clini-Temp Probe w/ Temp. Sensor	The Exac-Temp General Purpose Temperature Probe is to be used for routine monitoring of anesthetized patients by inserting the probe into the esophagus or rectum.	The Indications for Use have been updated for the proposed device to include the reference body site and measuring site as defined by ISO 80601-2-56 and the intended treatment population and compatible monitors as requested by the FDA.
	Adult Skin Sensor		K925006 – Exac-Temp Skin Surface Temperature Sensor	The Exac-Temp Skin Surface Temperature Sensor is to be used for routine monitoring of a patient's skin surface.	
	Tympanic Probe		K925792 – Exac-Temp & Clini-Temp Tympanic Probe	The Exac-Temp Tympanic Temperature Probe is to be used for routine monitoring of the patient temperature using the aural canal (ear canal or the external auditory meatus).	

		by insertion of the ear piece into the aural canal. The device is single use and for use by licensed healthcare practitioners only. The probes are designed to interface with DeRoyal-branded cables for connection with YSI 400 or 700 series compatible monitors, including the following patient monitors and equivalent models: Mindray Passport, Philips IntelliVue, Siemens/ Draeger Infinity, and GE Datex-Ohmeda brands.			
Prescription Only	General Purpose	Yes	K925791 – Exac-Temp & Clini-Temp Probe w/ Temp. Sensor	Yes	Same
	Adult Skin Sensor		K925006 – Exac-Temp Skin Surface Temperature Sensor		
	Tympanic Probe		K925792 – Exac-Temp & Clini-Temp Tympanic Probe		
Mode of Operation	General Purpose	Direct Mode	K925791 – Exac-Temp & Clini-Temp Probe w/ Temp. Sensor	Direct Mode	Same
	Adult Skin Sensor		K925006 – Exac-Temp Skin Surface Temperature Sensor		
	Tympanic Probe		K925792 – Exac-Temp & Clini-Temp Tympanic Probe		

Measuring Site	General Purpose	Rectum, Esophagus, Nasopharynx	K925791 – Exac-Temp & Clini-Temp Probe w/ Temp. Sensor	Esophagus, Rectum	DeRoyal intends to add the nasopharynx to the General Purpose Probe as a measuring site. ISO 80601-2-56 defines measuring site as the "part of the patient where the temperature is measured." The FDA has cleared three 510(k)s for temperature probes that utilize the nasopharynx as a measuring site in addition to the esophagus and rectum: K101244, K140134, and K181967.
	Adult Skin Sensor	Skin Surface	K925006 – Exac-Temp Skin Surface Temperature Sensor	Skin Surface	Same
	Tympanic Probe	Auditory Canal	K925792 – Exac-Temp & Clini-Temp Tympanic Probe	Auditory Canal	Same
Reference Body Site	General Purpose	Core Body	K925791 – Exac-Temp & Clini-Temp Probe w/ Temp. Sensor	Core Body	Same
	Adult Skin Sensor	Skin Surface	K925006 – Exac-Temp Skin Surface Temperature Sensor	Skin Surface	Same
	Tympanic Probe	Core Body	K925792 – Exac-Temp & Clini-Temp Tympanic Probe	Core Body	Same
Use Environment	General Purpose	Hospital	K925791 – Exac-Temp & Clini-Temp Probe w/ Temp. Sensor	Hospital	Same
	Adult Skin Sensor		K925006 – Exac-Temp Skin Surface Temperature Sensor		

	Tympanic Probe		K925792 – Exac-Temp & Clini-Temp Tympanic Probe		
Rated Output Range	General Purpose	25°C to 45°C	K925791 – Exac-Temp & Clini-Temp Probe w/ Temp. Sensor	25°C to 45°C	Same
	Adult Skin Sensor		K925006 – Exac-Temp Skin Surface Temperature Sensor		
	Tympanic Probe		K925792 – Exac-Temp & Clini-Temp Tympanic Probe		
Accuracy	General Purpose	±0.2°C	K925791 – Exac-Temp & Clini-Temp Probe w/ Temp. Sensor	±0.2°C	Same
	Adult Skin Sensor		K925006 – Exac-Temp Skin Surface Temperature Sensor		
	Tympanic Probe		K925792 – Exac-Temp & Clini-Temp Tympanic Probe		
Operating Conditions	General Purpose	25°C to 45°C	K925791 – Exac-Temp & Clini-Temp Probe w/ Temp. Sensor	25°C to 45°C	Same
	Adult Skin Sensor		K925006 – Exac-Temp Skin Surface Temperature Sensor		
	Tympanic Probe		K925792 – Exac-Temp & Clini-Temp Tympanic Probe		
Design	General Purpose	Wire set with a thermistor chip at the distal end and a blue connector at the proximal end. The wire set is enclosed in a tube that may be inserted into the application site.	K925791 – Exac-Temp & Clini-Temp Probe w/ Temp. Sensor	Wire set with a thermistor chip at the distal end and a blue connector at the proximal end. The wire set is enclosed in a tube that may be inserted into the application site.	Same
	Adult Skin Sensor	Wire set with a	K925006 – Exac-Temp	Wire set with a	Same

		thermistor chip at the distal end and a blue connector at the proximal end. An adhesive probe cover applies the device to the patients' skin.	Skin Surface Temperature Sensor	thermistor chip at the distal end and a blue connector at the proximal end. An adhesive probe cover applies the device to the patients' skin.	
	Tympanic Probe	Wire set with a thermistor chip at the distal end and a blue connector at the proximal end. A foam ear plug is used to insert the device into the patient's aural canal.	K925792 – Exac-Temp & Clini-Temp Tympanic Probe	Wire set with a thermistor chip at the distal end and a blue connector at the proximal end. A foam ear plug is used to insert the device into the patient's aural canal.	Same
Materials	General Purpose	Tube: PVC Wire: Copper with PVC insulation Thermistor: Ceramic Connector: PVC-molded brass Strain Relief: PVC Cap: UV-cured adhesive	K925791 – Exac-Temp & Clini-Temp Probe w/ Temp. Sensor	Tube: PVC Wire: Copper with PVC insulation Thermistor: Ceramic Connector: PVC-molded brass Strain Relief: PVC Cap: PVC and epoxy glue	The proposed device uses a UV-cured adhesive to replace the PVC cap and epoxy glue utilized in the predicate device to encapsulate the thermistor. In the General Purpose and Tympanic configurations, the UV-cured adhesive is non-patient contacting. In the Adult Skin configuration, it will directly touch the patient's intact skin. A biological risk assessment and testing were performed on the proposed products and are contained within Section 15 of the submission. Electrical
	Adult Skin Sensor	Cover: Adhesive foam Wire: Copper with PVC insulation Thermistor: Ceramic Connector: PVC-molded brass Strain Relief: PVC Cap: UV-cured adhesive	K925006 – Exac-Temp Skin Surface Temperature Sensor	Cover: Adhesive foam Wire: Copper with PVC insulation Thermistor: Ceramic Connector: PVC-molded brass Strain Relief: PVC Cap: PVC and epoxy glue	
	Tympanic Probe	Ear Plug: Foam and/or cotton ball Wire: Copper with PVC insulation Thermistor: Ceramic	K925792 – Exac-Temp & Clini-Temp Tympanic Probe	Ear Plug: Foam and/or cotton ball Wire: Copper with PVC insulation Thermistor: Ceramic	

		Connector: PVC-molded brass Strain Relief: PVC Cap: UV-cured adhesive		Connector: PVC-molded brass Strain Relief: PVC Cap: PVC and epoxy glue	Safety and EMC testing also were performed on the proposed device and are contained within Section 17. The results of this testing support the proposed device's safety and effectiveness.
Use of a Probe Cover	General Purpose	No	K925791 – Exac-Temp & Clini-Temp Probe w/ Temp. Sensor	No	Same
	Adult Skin Sensor	Yes	K925006 – Exac-Temp Skin Surface Temperature Sensor	Yes	Same
	Tympanic Probe	No	K925792 – Exac-Temp & Clini-Temp Tympanic Probe	No	Same
Nature of Body Contact	General Purpose	Mucosal Membrane	K925791 – Exac-Temp & Clini-Temp Probe w/ Temp. Sensor	Mucosal Membrane	Same
	Adult Skin Sensor	Intact Skin	K925006 – Exac-Temp Skin Surface Temperature Sensor	Intact Skin	Same
	Tympanic Probe	Intact Skin	K925792 – Exac-Temp & Clini-Temp Tympanic Probe	Intact Skin	Same
Duration of Contact	General Purpose	Limited (≤ 24 hours)	K925791 – Exac-Temp & Clini-Temp Probe w/ Temp. Sensor	Limited (≤ 24 hours)	Same
	Adult Skin Sensor	Prolonged (≥ 24 hours)	K925006 – Exac-Temp Skin Surface Temperature Sensor	Prolonged (≥ 24 hours)	Same
	Tympanic Probe	Prolonged (≥ 24 hours)	K925792 – Exac-Temp & Clini-Temp Tympanic Probe	Prolonged (≥ 24 hours)	Same
Sterilization	General Purpose	Sterilized with Ethylene Oxide	K925791 – Exac-Temp & Clini-Temp Probe w/ Temp. Sensor	Sterilized with Ethylene Oxide	Same

	Adult Skin Sensor	Sterilized with Ethylene Oxide	K925006 – Exac-Temp Skin Surface Temperature Sensor	Sterilized with Ethylene Oxide	Same
	Tympanic Probe	Non-sterile	K925792 – Exac-Temp & Clini-Temp Tympanic Probe	Non-sterile	Same
Storage Conditions	General Purpose Probe	-25°C to +55°C	K925791 – Exac-Temp & Clini-Temp Probe w/ Temp. Sensor	-25°C to +55°C	Same
	Adult Skin Sensor		K925006 – Exac-Temp Skin Surface Temperature Sensor		
	Tympanic Probe		K925792 – Exac-Temp & Clini-Temp Tympanic Probe		
Reusable or Disposable	General Purpose	Disposable	K925791 – Exac-Temp & Clini-Temp Probe w/ Temp. Sensor	Disposable	Same
	Adult Skin Sensor		K925006 – Exac-Temp Skin Surface Temperature Sensor		
	Tympanic Probe		K925792 – Exac-Temp & Clini-Temp Tympanic Probe		

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Summary of Performance Tests

The proposed device has been tested and/or evaluated according to the following standards: ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 80601-2-56, IEC 60601-1, and IEC 60601-1-2.

The following biocompatibility tests were performed on final, finished products manufactured with the proposed change: cytotoxicity, skin sensitization, and irritation. This testing was performed on each of the three configurations contained within this submission.

Testing according to IEC 60601-1 and IEC 60601-1-2 was performed to ensure the change in the encapsulation did not affect the electrical safety of the device. Accuracy and time response testing according to ISO 80601-2-56 was performed to ensure the proposed device completed its essential performance safely and effectively. A leakage current test also was performed after submerging the device in solution to ensure the encapsulation method is effective.

All testing was performed on final, finished products manufactured with the proposed modification. The test results met the requirements of the aforementioned standards and demonstrate that the proposed modification does not impact the safety or efficacy of the device.

Conclusion

The results of performance testing demonstrate the DeRoyal Temperature Monitoring Probe is substantially equivalent to the predicates. With the exception of the proposed change to the encapsulation method, the proposed device is identical to the predicate devices, which have been on the market since 1994. Therefore, the proposed device is substantially equivalent to the predicate.