October 15, 2020

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

Re: K200757
Trade/Device Name: Foley Catheter with Temperature Sensor
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EYC, EZL
Dated: September 11, 2020
Received: September 14, 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,

Sharon Andrews
Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
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)*
K200757

Device Name
Foley Catheter with Temperature Sensor

Indications for Use *(Describe)*
The DeRoyal Foley Catheter with Temperature Sensor is to be used for drainage of the urinary bladder and simultaneous monitoring of core body 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.

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200 DeBusk Lane
Powell, TN 37849 USA
865.938.7828
800.251.9864
www.deroyal.com

DeRoyal Industries, Inc.
Traditional 510(k) Submission – Foley Catheter with Temperature Sensor
March 23, 2020

510(k) Summary

Date prepared:	March 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:	Xeridiem Medical Devices 4700 S Overland Dr Tuscon, AZ 85714 DeRoyal Cientifica de Latinoamerica S.R.L. Global Park Box 180-3006, 602 Parkway La Aurora, Heredia Heredia, Costa Rica 146
Trade Name:	Foley Catheter with Temperature Sensor
Common Name:	Foley Catheter with Temperature Sensor
Classification Name:	Urological Catheter and accessories
Classification:	Class II
Device Product Code:	EYC, EZL
Classification Panel:	Gastroenterology/Urology
Regulation Number:	21 CFR 876.5130
Predicate Devices:	EXAC-TEMP Foley Catheter and CLINI-TEMP Foley Catheter [K041416]

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Device Description

The Foley Catheter with Temperature Sensor is used for drainage of the urinary bladder and simultaneous monitoring of core body temperature. The device consists of a temperature-sensing wire set secured inside the lumen of a silicone Foley catheter. It is available in 14, 16, and 18 French size catheters. The French size and balloon volume are designated on the device itself.

The wire set contains a thermistor chip, which is located near the distal tip of the catheter. The thermistor passively modifies the electrical current traveling through the wire set. A blue connector is located at the proximal end of the device. This connector interfaces with a cable that is connected to an independent temperature monitor used to display temperature readings.

The catheters are individually packaged and sold sterile.

The subject device is identical to the predicate device with the exception of the encapsulation method of the thermistor chip.

Indications for Use

The DeRoyal Foley Catheter with Temperature Sensor is to be used for drainage of the urinary bladder and simultaneous monitoring of core body temperature.

Summary of Technological Characteristics

Characteristic	**Foley Catheter w/ Temperature Sensor (Proposed Device)**	**EXAC-TEMP Foley Catheter and CLINI- TEMP Foley Catheter [K041416]**
Indications for Use	The DeRoyal Foley Catheter with Temperature Sensor is to be used for drainage of the urinary bladder and simultaneous monitoring of core body temperature.	DeRoyal Exac- Temp and Clini- Temp Foley Catheter with Temperature Sensors are to be used for drainage of the urinary bladder and simultaneous monitoring of temperature.

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Patient Population	Male and female adults	Male and female adults and pediatrics
Use Environment	Hospital	Hospital
Prescription Only	Yes	Yes
French Size	14-18 French	8-18 French
Length	Tip to funnel: 17.75 in Tip to connector: 30.75 in	For 14-18 French catheters Tip to funnel: 17.75 in Tip to connector: 30.75 in
Number of Lumens	3	3
Balloon Size	5 cc	3 or 5 cc
Single Use	Yes	Yes
Mode of Operation	Direct according to ISO 80601-2-56	Direct according to ISO 80601-2-56
Measuring Site	Urinary bladder	Urinary bladder
Reference Body Site	Core body	Core body
Design	A wire set with a thermistor chip at the distal end and a blue connector at the proximal end inserted inside a silicone Foley catheter.	A wire set with a thermistor chip at the distal end and a blue connector at the proximal end inserted inside a silicone Foley catheter.
Materials	Wire Set: Copper wire with PVC insulation, ceramic thermistor, PVC-mold brass connector, UV-curing adhesive	Wire Set: Copper wire with PVC insulation, ceramic thermistor, PVC-mold brass connector, PVC and epoxy glue

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	cap, and PVC strain relief Foley Catheter: Silicone catheter with a polypropylene inflation valve and ABS collar	cap, and PVC strain relief Foley Catheter: Silicone catheter with a polypropylene inflation valve and ABS collar

The subject and predicate device have the same indications for use statement but different technological characteristics as described in the table above. The different technological characteristics doe not raise different questions of safety and effectiveness.

Summary of Performance Tests

The following biocompatibility tests were performed on final, finished products manufactured with the proposed change: cytotoxicity, skin sensitization, irritation, material-mediated pyrogenicity, and acute systemic toxicity per I SO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11. Implantation testing according to ISO 10993-6 was performed on a predicate device and was not repeated because the testing was performed according to the current recognized version of the standard and the proposed change is to a non-patient contacting device component.

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 acceptance criteria of the aforementioned standards.

Conclusion

The results of performance testing demonstrate the Foley Catheter with Temperature Sensor is as safe and effective as the predicate. The proposed device is substantially equivalent to the predicate.