April 2, 2020

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

Re: K193027
Trade/Device Name: Esophageal Stethoscope with Temperature Sensors
Regulation Number: 21 CFR 868.1920
Regulation Name: Esophageal Stethoscope with Electrical Conductors
Regulatory Class: Class II
Product Code: BZT
Dated: February 25, 2020
Received: February 27, 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 post-marketing 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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental 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)*
K193027

Device Name
Esophageal Stethoscope with Temperature Sensor

Indications for Use *(Describe)*
The DeRoyal Esophageal Stethoscope with Temperature Sensor is to be used for routine monitoring of core body temperature, as well as heart and respiratory sounds in an anesthetized patient by inserting the stethoscope tube into the esophagus.

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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DeRoyal Industries, Inc.
Traditional 510(k) Submission – Esophageal Stethoscope with Temperature Sensor
October 25, 2019

510(k) Summary

Date prepared:	October 25, 2019
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
Trade Name:	Esophageal Stethoscope with Temperature Sensor
Common Name:	Esophageal Stethoscope with Temperature Sensor
Classification Name:	Stethoscope, Esophageal, with Electrical Conductors
Device Class:	Class II
Device Product Code:	BZT
Regulation Number:	21 CFR 868.1920
Classification Panel:	Anesthesiology
Predicate Devices:	DeBusk Temperature Systems Esophageal Stethoscope [K925789]

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Device Description
The DeRoyal Esophageal Stethoscope with Temperature Sensor is inserted into the esophagus of anesthetized patients to monitor core body temperature as well as heart and respiratory sounds. The probe consists of a small diameter plastic tube upon which a blue cuff is placed. When inserted in the esophagus, the cuff facilitates transmission of sound to an ear piece attached at the proximal end of the tube. Additionally, a wire set is placed inside the plastic tube. This wire set contains a thermistor chip at the distal end that passively modifies the electrical current traveling through the probe. A blue connector at the proximal end of the wire set interfaces with a cable that is connected to an independent temperature monitor that is used to display the temperature readings.

The probe is sterile and individually packaged. It is available in 9, 12, 18, and 24 French sizes and may come with 400 or 700 series sensors. The stethoscope has a male luer fitting for attachment to standard ear pieces.

Intended Use
The DeRoyal Esophageal Stethoscope with Temperature Sensor is to be used for routine monitoring of core body temperature, as well as heart and respiratory sounds, in an anesthetized patient by inserting the stethoscope tube into the esophagus.

Summary of Technological Characteristics

Characteristic	**DeRoyal Esophageal Stethoscope with Temperature Sensor**	**DeBusk Temperature Systems Esophageal Stethoscope (K925789)**
Indications for Use	The DeRoyal Esophageal Stethoscope with Temperature Sensor is to be used for routine monitoring of core body temperature, as well as heart and respiratory sounds, in an anesthetized patient by inserting the stethoscope tube into the esophagus.	The EXAC-TEMP Esophageal Stethoscope with temperature sensor is to be used for routine monitoring of temperature, as well as for heart and respiratory sounds, in an anesthetized patient by inserting the stethoscope tube into the esophagus.
Prescription Only	Yes	Yes

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Mode of Operation	Direct according to ISO 80601-2-56	Direct according to ISO 80601-2-56
Measuring Site	Esophagus	Esophagus
Reference Body Site	Core body temperature	Core body temperature
Use Environment	Hospital	Hospital
Design	A wire set inserted into a plastic tube with a blue cuff at the distal end. The wire set has a thermistor chip at the distal end and a blue connector at the proximal end.	A wire set inserted into a plastic tube with a blue cuff at the distal end. The wire set has a thermistor chip at the distal end and a blue connector at the proximal end.
Materials	Tube – PVC Cuff – PVC Wire – Copper with PVC insulation Thermistor – Ceramic Ear Piece – K-Resin Connector – PVC-molded brass Strain Relief – PVC Cap – UV-Curing Adhesive	Tube – PVC Cuff – PVC Wire – Copper with PVC insulation Thermistor – Ceramic Ear Piece – K-Resin Connector – PVC-molded brass Strain Relief – PVC Cap – PVC and epoxy glue
Accuracy	±0.2°C	±0.2°C
Sterilization	Sterilized with ethylene oxide	Sterilized with ethylene oxide
Biocompatibility	ISO 10993-1 compliant	ISO 10993-1 compliant

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

The following biocompatibility tests were performed on the predicate device: cytotoxicity, skin sensitization, irritation, acute systemic toxicity, and material-mediated pyrogenicity. The proposed change was evaluated in a biological risk assessment, and it was determined that, because the change is to a non-patient contacting material that does not directly or indirectly contact tissue, it was unnecessary to perform new testing on a device manufactured with the proposed encapsulation method.

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

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testing according to ISO 80601-2-56 were performed to ensure the proposed device performed its essential performance safely and effectively. A leakague current test also was performed after submerging the device in solution to ensure the encapsulation method is effective. Additionally, an acoustic responsiveness test was done to demonstrate the proposed change did not affect the stethoscope functions of the device.

All testing was performed on a final, finished device 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 Esophageal Stethoscope with Temperature Sensor do not raise different questions of safety or effectiveness. With the exception of the proposed change to the encapsulation method, the proposed device is identical to the predicate, which has been on the market since 1993. Therefore, the proposed device is substantially equivalent to the predicate.