DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

August 17, 2017

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

Re: K171475
Trade/Device Name: DeRoyal Laprador Specimen Retrieval System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 11, 2017
Received: August 14, 2017

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171475

Device Name
DeRoyal Laprador Specimen Retrieval System

Indications for Use *(Describe)*
The DeRoyal Laprador Specimen Retrieval System is a sterile device intended to be used for collection and extraction of tissue, organs, and calculi during laparoscopic surgical procedures.

Contraindications
The DeRoyal Laprador Specimen Retrieval System is contraindicated for use when, in the judgment of the licensed clinician, use of such a device would not be in the best interest of the patient.

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 – DeRoyal Laprador Specimen Retrieval System
May 18, 2017

510(k) Summary

Date prepared:	May 18, 2017
510(k) Owner:	DeRoyal Industries, Inc. 200 DeBusk Lane Powell, TN 37849 Owner/Operator #1044833
510(k) Contact:	Sarah Bennett Regulatory Affairs Specialist P: 865-362-6112 F: 865-362-3741 sabennett@deroyal.com
Contract Manufacturer:	DeRoyal Intercontinental, S.R.L. Km 7, Autopista Joaquin Balaguer Pisano Free Zone, Building 49 Santiago Santiago, DO FDA Establishment #3004605321
Trade Name:	DeRoyal Laprador Specimen Retrieval System
Common Name:	Specimen Retrieval Bag
Classification Name:	Laparoscope, General & Plastic Surgery (21 CFR 876.1500)
Regulatory Class:	Class II
Device Product Code:	GCJ
Classification Panel:	General & Plastic Surgery
Predicate Devices:	Anchor Laparoscopic Tissue Retrieval System [K091930]

Device Description
The DeRoyal Laprador Specimen Retrieval System consists of a handle, a cylindrical tube, a string, and a ripstop nylon bag. The system deploys and retracts the nylon bag, which encloses tissue specimens for retrieval during laparoscopic surgical procedures.

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The device is designed for introduction and use through appropriately sized trocars. The device is sterilized by ethylene oxide.

Intended Use

The DeRoyal Laprador Specimen Retrieval System is a sterile device intended to be used for collection and extraction of tissue, organs, and calculi during laparoscopic surgical procedures.

Summary of Technological Characteristics

The intended use and design are identical to the predicate devices. The proposed device is sterilized by ethylene oxide and utilizes a rip-stop nylon material for the bag construction. This sterilization method and bag material are identical to the method and bag material utilized by the Anchor Tissue Retrieval System (K091930). The mechanisms to load the tissue bag into the introducer shaft and separate the bag from the deployment shaft are different; however, bench test results demonstrate these differences do not raise new issues of safety and effectiveness. The proposed device is substantially equivalent as it poses no new changes that could impact safety and effectiveness.

Characteristic	**DeRoyal Laprador Specimen Retrieval System**	**Predicate Device Anchor K091930**
Intended Use	Intended for collection and extraction of tissue, organs, and calculi during laparoscopic surgical procedures.	Same
Where Used	Operating Room	Same
Prescription Only	Yes	Same
Design	Specimen bag and a delivery system consisting of an introducer shaft and deployment handle	Same
Materials	Nylon bag and cinch string, polyester stitching, ABS handles and shaft, and stainless steel rod and spring	Nylon bag, plastic handles tubes and rods
Mechanism to load tissue bag into introducer shaft	Pull Tail hook loop	Hook and spring mechanism at distal end.
Mechanism to	Rotating hook	Push button

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separate bag from deployment shaft		
Performance	There are no FDA performance standards for this device. Therefore, bench testing was performed.	Same
Sterilization	Ethylene Oxide per ISO 11135-1: 2014	Same
Biocompatibility	According to ISO 10993-1: 2009	Same

Summary of Performance Tests
Bench testing was completed to ensure the device meets its performance specifications and functions effectively. Device characteristics tested included device pressure leak rate, bag leakage and volume, bag puncture resistance, bag burst resistance, retraction and deployment functionality, and cinch string strength. All tests were performed on the DeRoyal Laprador Specimen Retrieval system, the predicate device, and an additional competitor, Applied Medical Specimen Retrieval System (K100959). The proposed device passed all design verification tests and performed comparable to at least one competitor device, thus demonstrating it meets performance specifications and functions safe and effectively.

Conclusion
The results of the performance and comparative testing demonstrate the DeRoyal Laprador Specimen Retrieval System is substantially equivalent to the predicate devices, the Anchor Tissue Retrieval System cleared under K091930.