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510(k) SUMMARY: DEROYAL INDUSTRIES, INC. DISPOSABLE SURGICAL TROCAR/CANNULA

(1) DeRoyal Industries
200 DeBusk Lane
Powell, TN 37849

Contact Person:	Camille Matlock
Telephone:	(423) 938-7828
Date Summary Prepared:	December 18, 1997

(2) Trade or Proprietary Name: none established

Common Name (s):	Disposable Surgical Trocar/Cannula
	Disposable Surgical Blunt tip Trocar/Cannula
Classified Name:	Endoscope and accessories, § 876.1500, Class II

(3) Predicates: Auto Suture® Surgiport® Disposable Trocar & Sleeve (510(k) nos. K862611, K874879, K900487, K903419)

Ethicon Endopath Disposable Surgical Trocar and Sleeve (510(k) nos. K912398, K924035, K932282)

(4) Description of Device:

The DeRoyal Disposable Surgical Trocar/Cannula is a disposable single patient use device fabricated from surgical grade stainless steels, surgical grade aluminum, and biocompatible medical grade polymers.

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The device comes in 5, 8, 10/11, and 12 mm diameter cannulas. Cannula length ranges from 75 mm - 100 mm. The cannula diameter can be used with equivalent diameter instruments or scopes, but is also equipped with a detachable integrated reducer diaphragm on all large sizes to bring the compatible diameter down to 5 mm. The trocar/cannula is supplied with either a pyramidal tip cutting trocar with safety shield or with a blunt tip trocar/cannula without safety shield for use with open laparoscopic procedures. The cutting trocar/cannula has a tri-segmented safety shield which is comprised of three shield segments that retract and advance independently.

The cannula body has a luer fitting to accommodate insufflation apparatus and an external lever for manual opening of the internal flapper valve for rapid desufflation. The cannula shaft is radiotranslucent.

(5) Intended Use:

The DeRoyal Disposable Surgical Trocar/Cannula is a single patient use disposable device intended for use during operative and/or diagnostic surgery to puncture/penetrate the abdominal wall and to serve as a port of entry for laparoscopic instruments (i.e., laparoscope, forceps, scissors, aspiration/irrigation cannula, etc.).

(6) Technological Characteristics:

Characteristics	Predicate Devices	**DeRoyal Industries**
Intended Use	Application in thoracic, gynecologic laparoscopy, and other abdominal procedures to establish a path of entry for endoscopic instruments.	Same
Pyramidal Tip	Yes	Same
Safety Shield	Yes	Same
Reducer to Accommodate Smaller Instruments	Yes	Same
Sterility	Sterile	Same
Materials	Polymers, silicone rubber, stainless steel, and aluminum.	Polymers, silicone rubber, fiberglass, stainless steel, and aluminum.

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The DeRoyal Disposable Surgical Trocar/Cannula has similar/same technological characteristics as the predicate devices in that they are comprised of similar design, materials, and are intended to be used as a port of entry for laparoscopic instruments.

(7) Conclusion:

The proposed device has the same intended use and the same basic technology as the legally marketed predicate devices identified in the premarket notification submission. The proposed device contains, in some combination, similar/same features, materials, and design as the predicate devices and does not pose any new questions concerning safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Camille Matlock
Regulatory Affairs
DeROYAL Industries, Inc.
200 DeBusk Lane
Powell, TN 37849

Re: K974763
Disposable Surgical Trocar/Cannula
Dated: April 16, 1998
Received: April 17, 1998
Regulatory Class: II
21 CFR 884.1720/Procode: 85 HET

Dear Ms. Matlock:

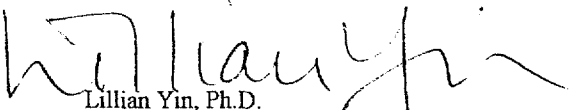
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K974763

Device Name: Disposable Surgical Trocar/Cannula

Indications for Use:

The DeRoyal Industries Disposable Surgical Trocar/Cannula is a single patient use disposable device intended for use during operative and/or diagnostic surgery to puncture/penetrate the abdominal wall and to serve as a port of entry for laparoscopic instruments (i.e. laparoscope, forceps, scissors, aspiration/irrigation cannula, etc.).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Satterfield

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974763

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR § 801.109)