

MAY 22 1997

DeRoyal Industries, Inc.

**DISPOSABLE BIPOLAR ELECTROSURGICAL CABLE**

**510(k) Summary**

K970893

**Summary of the Safety and Effectiveness Information  
Upon Which  
An Equivalence Determination Could Be Based**

**SUBMITTER INFORMATION**

<b>NAME:</b>	DeRoyal Industries, Inc.	<b>TELEPHONE:</b>	(423) 938-7828
<b>ADDRESS:</b>	200 DeBusk Lane	<b>CONTACT:</b>	Maria Ebio
	Powell, TN 37849	<b>DATE OF PREPARATION:</b>	March 18, 1997

**DEVICE NAMES**

<b>NAME:</b>	DeRoyal Industries, Inc. Disposable Bipolar Electrosurgical Cable
<b>COMMON/USUAL NAME:</b>	Bipolar Cable/Cord
<b>CLASSIFICATION NAME (if known):</b>	Electrosurgical Cutting & Coagulation Device and Accessories (79 GEI)

**PREDICATE OR LEGALLY MARKETED DEVICES**

American Biosurgical, Apple Medical, Birtcher Medical Systems, Codman, Conmed, Kirwan, Olsen, Pilling Weck, and Valleylab

**DEVICE DESCRIPTION**

The DeRoyal Industries, Inc. Disposable Bipolar Electrosurgical Cable functions in the same manner as predicate devices in that it is intended to be used in electrosurgical procedures to provide transmission of electrical power from an electrosurgical generator to a bipolar instrument.

Device Design/ Materials Used/Physical Properties: The DeRoyal Industries, Inc. Disposable Bipolar Electrosurgical Cable is made of materials commonly used for their purpose. The primary material components are made of polyvinyl chloride.

**DEVICE INTENDED USE**

The DeRoyal Industries, Inc. Disposable Bipolar Electrosurgical Cable is intended for use in electrosurgical procedures to provide transmission of electrical power from an electrosurgical generator to a bipolar instrument.

**TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETED DEVICE(S)**

Characteristic	DeRoyal Device	Other Devices
Length of Cable	12 ft. (366 cm.)	12 ft. (366 cm.)
Material of Outer Cable Insulation	PVC	PVC
Disposable	Yes	Yes
Sterility	Sterile	Sterile



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 22 1997

Ms. Maria Ebio  
Regulatory Affairs  
DeRoyal Industries, Inc.  
200 DeBusk Lane  
Powell, Tennessee 37849

Re: K970993  
Trade Name: DeRoyal Industries, Inc. Disposable Bipolar Electrosurgical Cable  
Regulatory Class: II  
Product Code: GEI  
Dated: March 18, 1997  
Received: March 19, 1997

Dear Ms. Ebio:

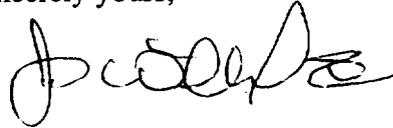
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4595. 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/dsmamain.html>".

Sincerely yours,



 Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K970993

Device Name: DeRoyal Industries, Inc. Disposable Bipolar Electrosurgical Cable

**Indications for Use:**

The DeRoyal Industries, Inc. Disposable Bipolar Electrosurgical Cable is indicated for use during electrosurgical procedures to provide transmission of electrical power from an electrosurgical generator to a bipolar instrument.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K970993

Prescription Use f  
(Per 21 CFR §801.109)

OR Over-The-Counter Use \_\_\_\_\_