K981239

MAY 14 1998

510(k) SUMMARY: DeRoyal Industries, Inc. Disposable Laparoscopic Clip Applier with Implantable Titanium Clips

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

Contact Person:	Camille Matlock
Telephone:	(423) 938-7828
Date Summary Prepared:	April 1, 1998

(2)	Trade or Proprietary Name:	DeRoyal Industries Disposable Laparoscopic Clip Applier with Implantable Titanium Clips
	Common Name:	Disposable Laparoscopic Clip Applier with Implantable Titanium Clips
	Classified Name:	Implantable Clip (74FZP, 21 CFR § 878.4300), Class II Endoscope and accessories, (78KOG, 21 CFR § 878.1500), Class II
(3)	Predicates:	United States Surgical Corporation (Ethicon Pilling Weck (formerly Edward Weck))

(4) Description of Device:

The DeRoyal Disposable Laparoscopic Clip Applier with Implantable Titanium Clips is a disposable single patient use device fabricated from biocompatible stainless steels and biocompatible medical grade polymers. The Disposable Clip Applier contains up to 20 implantable titanium clips. The closed clip length is approximately 9 mm. The intended use of the device is to occlude vessels and other tubular structures during laparoscopic surgical procedures. The clip applier jaws, with the open clip in the jaws, is placed around the vessel or other tubular structure. Actuation/compression of the clip applier handle/trigger drives a mechanism within the device to close the jaws, thereby forming the clip securely around the vessel. Release/decompression of the clip applier handle/trigger allows the jaws to open and release the clip. The automatic feed feature releases the next clip into the jaws for another application.

The shaft of the applier is sized to fit through a 10 mm cannula. The overall shaft length is approximately 33 mm and consistent with other endoscopic instruments.

(5) Intended Use:

The DeRoyal Disposable Clip Applier with Implantable Titanium Clips is intended for use during laparoscopic surgery to occlude a variety of vessels or other tubular structures.

(6) Technological Characteristics:

Characteristics	Predicate Devices	**DeRoyal Industries**
Intended Use	Endoscopic procedures to achieve occlusion of vessels and other tubular structures.	**Same**
Clip Surface	Textured	**Same**
Laparoscopic Intro. Size	≅10 MM	**Same**
Clip Dimensions	≅9 MM	**Same**
Sterility	Sterile	**Same**
Materials	Polymers, stainless steel, and black chrome coating.	**Same**

The DeRoyal Disposable Clip Applier with Implantable Titanium Clips has similar/same technological characteristics as the predicate devices in that they are comprised of similar design, similar materials, and are intended to be used to clip vessels or tubular structures during laparoscopic surgery.

(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

MAY 14 1998

Ms. Camille Matlock
Regulatory Affairs
DeRoyal Industries, Incorporated
200 DeBusk Lane
Powell, Tennessee 37849

Re: K981239
Trade Name: Disposable Laparoscopic Clip Applier with Implantable Titanium Clips
Regulatory Class: II
Product Code: FZP and KOG
Dated: April 1, 1998
Received: April 3, 1998

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 requirement, 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) 594-4595. 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): K981239

Device Name: Disposable Laparoscopic Clip Applier with Implantable Titanium Clips

Indications for Use:

The DeRoyal Industries Disposable Laparoscopic Clip Applier with Implantable Titanium Clips is intended for use in a variety of laparoscopic procedures to occlude tubular structures and vessels. The tissue being ligated should be consistent with the size of the clip.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981239

Prescription Use X
(Per 21 CFR § 801.109)

OR

Over-The-Counter Use _____