K060623

510k Summary

Name:	Cook Ireland
Address:	O' Holloran Road National Technology Park Limerick Ireland
Phone: Fax:	353 61 334440 353 61 334441
Contact Person:	Emmett Devereux, Quality & Regulatory Manager Sinead Burke, Regulatory Affairs Specialist

Date:	August 10, 2006
Trade Name:	ShortShot Saeed Hemorrhoidal Multi-Band Ligator with TriView Anoscope
Common Name:	Hemorrhoidal Multiple Band Ligator Anoscope
Classification Name:	Ligator, Hemorrhoidal, GU, 78FHN Anoscope, Non Powered, GU, FER
Legally Marketed Devices:	Wilson-Cook Multiple Band Ligator (K020526) O'Regan Disposable Anoscope (K020702)
Description of the Device:	The ShortShot Saeed Hemorrhoidal Multi-Band Ligator consists of a polycarbonate barrel attached to the tip of a polycarbonate handle. The barrel is preloaded with four (4) latex rubber ligation bands, and a trigger cord is utilized for deployment of the bands. The TriView Anoscope consists of transparent polystyrene Anoscope and Obturator. The TriView Anoscope enables the physician to dilate the anal canal, to complete a visual examination of the anal-rectal anatomy, and isolate the internal hemorrhoids for ligation using the ShortShot Saeed Hemorrhoidal Multi-Band Ligator.

Intended use:	The ShortShot Saeed Hemorrhoidal MultiBand Ligator with TriView Anoscope is used to ligate internal hemorrhoids facilitated by an anoscope, for use in adult patients only.
Comparison of Characteristics:	We believe the proposed Anoscope component of the device to be substantially equivalent to the currently marketed predicate device as cleared by K020702. We believe the proposed Ligator component of the device to be identical to the currently marketed predicate device as cleared by K020526.
Performance Data:	We believe the proposed device to be substantially equivalent to the named predicate devices in terms Intended Use, Indications for Use, performance characteristics tested and sterility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Sinead Burke
Regulatory Affairs Specialist
Cook Ireland Ltd.
O'Halloran Road
National Technology Park
Limerick
IRELAND

SEP - 6 2006

Re: K060623
Trade/Device Name: ShortShot Saeed Hemorrhoidal Multi-Band Ligator with TriView Anoscope
Regulation Number: 21 CFR §876.4400
Regulation Name: Hemorrhoidal ligator
Product Codes: FHN
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Product Code: FER
Regulatory Class: II
Dated: August 10, 2006
Received: August 14, 2006

Dear Ms. Burke:

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.

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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060623

Device Name: ShortShot Saeed Hemorrhoidal Multi-Band Ligator with TriView Anoscope

Indications for Use:

The ShortShot Saeed Hemorrhoidal MultiBand Ligator with TriView Anoscope is used to ligate internal hemorrhoids facilitated by an anoscope, for use in adult patients only.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060623