MAR 3 1 2005

COOK®

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K050294

510(k) Summary

Submitted By:

Cook Ireland Ltd.
O'Halloran Road,
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Limerick,
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Contact Information:

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Date Prepared: February 3, 2005

510(k) #: _____

Device:

Trade Name:	Sonnet ™ Polypectomy Snare
Common/Usual Name:	Snare
Class:	Class II
Product Code:	FDI

Intended Use:
The Sonnet ™ Polypectomy Snare is a monopolar electrosurgical device used with an electrical unit for endoscopic polypectomy.

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Device Description:
The Sonnet™ Polypectomy Snare consists of a 240cm catheter attached to a handle at the proximal end and incorporates a braided stainless steel wire in a loop configuration that is attached to a stainless steel drive-wire and is extendable and retractable with respect to the catheter distal tip. The handle provides an active cord connection. The catheter has a single lumen.

Test Data:
Tests include electrical testing

Substantial Equivalence:
The subject device is similar with respect to intended use and/or design features to the predicate devices in terms of section 510(k) substantial equivalence. The subject device is safe and effective and is substantially equivalent to the predicate devices.

Manufacturer	Device	510(k)
Wilson-Cook	Wilson-Cook Snare	K851958
Horizons International Corp.	Horizons Polypectomy Snare	K011667

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2005

Mr. Emmett Devereux
QA/RA Manager
Cook® Ireland Limited
O'Halloran Road
National Technology Park
LIMERICK IRELAND

Re: K050294
Trade/Device Name: Sonnet™ Polypectomy Snare
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: FDI
Dated: February 3, 2005
Received: February 7, 2005

Dear Mr. Devereux:

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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

510(k) Number (if known): K050294

Device Name: Sonnet™ Polypectomy Snare

Indications for Use:

The Sonnet ™ Polypectomy Snare is a monopolar electrosurgical device used with an electrical unit for endoscopic polypectomy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Only ✓ OR Over-the-Counter ~~Counter~~

(Per 21 CFR § 801.109

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050294