MAY 8 2007

Section 5.0 510(k) Summary

K063742

Name:	Cook Ireland Ltd
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Contact Persons:	Emmett Devereux, Quality & Regulatory Manager Sinead Burke, Regulatory Affairs Supervisor
Phone:	353 61 334440
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Date:	December 14, 2006
Trade Name:	Resonance™ Metallic Ureteral stent
Common Name:	Ureteral stent
Classification Name:	Stent, ureteral
Legally Marketed Devices:	Bioteq Double Pigtail Ureteral Stent set (K033210) Cook Endo-Sof™ Double Pigtail Stent (K961446)
Description of the Device:	The Resonance™ Metallic ureteral stent is a device which is intended to achieve normal urine flow from the kidney to the urinary bladder in situations where obstructive pathological processes prevent it. The stent extends from the renal pelvis to the urinary bladder via the ureter and is placed by either endoscopic retrograde or percutaneous antegrade insertion.

Indications for use:	Used for temporary stenting of the ureter in adult patients with extrinsic ureteral obstruction. Intended for one-time use only.
Comparison of Characteristics:	We believe the proposed device the Resonance ™ Metallic ureteral stent to be substantially equivalent to the currently marketed predicate devices Bioteq Double Pigtail Ureteral Stent set as cleared by (K033210) and Endo-Sof™ Double Pigtail Stent as cleared under (K961446).
Performance Data:	Non clinical testing was carried out on the stent to determine the equivalence of the Resonance ™ Metallic ureteral stent to the predicate devices and to verify the safety and effectiveness of the stent. The following is a summary of the testing carried out: flow, elongation / yield and tensile strength, stent migration and retention. Clinical testing was carried out to primarily gather information on adverse events and stent function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 8 2007

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

Re: K063742
Trade/Device Name: Resonance™ Metallic Ureteral Stent
Regulation Number: 21 CFR §876.4620
Regulation Name: Ureteral stent
Regulatory Class: II
Product Code: FAD
Dated: April 23, 2007
Received: April 26, 2007

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.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/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

Section 4.0 Indications for Use

510(k) Number (if known): K063742

Device Name: Resonance™ Metallic Ureteral stent

Indications for Use:

Used for temporary stenting of the ureter in adult patients with extrinsic ureteral obstruction. Intended for one-time use only.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K063742