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COOK®

OCT 1 1 2005

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510(k) Summary

SPONSOR:

Cook Ireland Ltd.
O'Halloran Road,
National Technology Park,
Limerick,
Ireland

Contact Submitter:

Emmett Devereux
QA/RA Manager
Cook Ireland Limited
O'Halloran Road
National Technology Park
Limerick, Ireland
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Email: edevereux@cook.ie

Date of Submission: August 19, 2005

Device: **EchoBrush™**
Trade Name: Cook Ireland EchoBrush ™
Common/Usual Name: Endoscopic Ultrasound Cytology Brush
Class: Brush Cytology, For Endoscope 21 CFR§ 876.1500, FDX

Predicate Device: Wilson-Cook GI Aspiration Needle, K934356
Wilson-Cook Biliary Cytology Brush, K040324

Intended Use: The EchoBrush™ is used to sample targeted submucosal gastrointestinal lesions through the accessory channel of an ultrasound endoscope.

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Device Description:
The EchoBrush™ consists of a cytology brush for sampling submucosal gastrointestinal lesions. There is a handle attached to the proximal end of the device. The handle can be attached and locked onto the ECHO-19 Ultrasound needle. A white piece of shrink tube can be seen for a length of 9mm from the handle along the nitinol shaft. This will indicate to the user that the brush is about exit the tip of the needle.

Comparison of Characteristics:
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.

Test Data:
Non-Clinical testing was performed on characteristics and operational functions of the EchoBrush™ deemed necessary to verify safety and performance.

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Genotoxicity (Ames Test): The results of this test indicated that under the experimental conditions, the extracts of this test article were not mutagenic for any tester strain, with or without any S9 activation.

Mentor also performed chemical testing to support a 36 month shelf life for the SCHG.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 1 2005

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

Re: K052279
Trade/Device Name: Cook Ireland EchoBrush™
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDX
Dated: August 19, 2005
Received: August 22, 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/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

510(k) Number (if known): K052279

Device Name: EchoBrush™

Indications for Use:

The EchoBrush™ is used to sample targeted submucosal gastrointestinal lesions through the accessory channel of an ultrasound endoscope.

(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 _____
(Per 21 CFR § 801.109)

David A. Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052279