Section 5.0 510(k) Summary

K092359

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Contact Persons:	Emmett Devereux, Quality & Regulatory Manager Tracy Moriarty, Regulatory Affairs Specialist
Phone:	353 61 334440
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Date:	31st July 2009
Trade Name:	EchoTip® Ultra High Definition Ultrasound Access Needle
Common Name:	Endoscopic Ultrasound Needle
Classification Name:	Kit, needle, biopsy (21 CFR 876.1075, Product Code: FCG)
Legally Marketed Devices:	EchoTip® Ultra Ultrasound Needle (K083330) Wilson-Cook Cystotome™ Needle Knife (K022595)
Description of the Device:	The EchoTip® Ultra High Definition Ultrasound Access Needle is a 19 gauge endoscopic ultrasound needle with a stylet and a needle. The needle is dimpled for improved ultrasonic visualization and is advanced through the accessory channel of an ultrasound endoscope to the target site. The preloaded stylet is used to puncture the target site and aid in inserting the needle. The stylet is withdrawn from the needle. Fine needle injection (FNI), fine needle aspiration (FNA) or access to the target site can then be performed.
Indications for use:	This device is used to access or sample submucosal and extramural lesions of the gastrointestinal tract, access of the following:

	the intra- or extra-hepatic bile ducts, pancreatic ducts, cystic duct, gallbladder or for delivery of injectable materials into tissues through the accessory channel of an ultrasound endoscope.
Comparison of Characteristics:	The EchoTip® Ultra High Definition Ultrasound Access Needle is substantially equivalent to the currently marketed predicate devices: the EchoTip® Ultra Ultrasound Needle (K083330) and the Wilson-Cook Cystotome™ Needle Knife (K022595)
Performance Data:	Non-clinical testing was carried out on the device to determine the equivalence of the EchoTip® Ultra High Definition Ultrasound Access Needle to the predicate devices and to provide assurance of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Tracy Moriarty
Regulatory Affairs Specialist
Cook Ireland Ltd.
O'Halloran Road
National Technology Park
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NOV - 2 2009

Re: K092359
Trade/Device Name: EchoTip® Ultra High Definition Ultrasound Access Needle
Regulation Number: 21 CFR §876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: FCG
Dated: July 31, 2009
Received: August 4, 2009

Dear Ms. Moriarty:

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 (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting 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): K092359

Device Name: EchoTip® Ultra High Definition Ultrasound Access Needle

Indications for Use:

This device is used to access or sample submucosal and extramural lesions of the gastrointestinal tract, access of the following: the intra- or extra-hepatic bile ducts, pancreatic ducts, cystic duct, gallbladder or for delivery of injectable materials into tissues through the accessory channel of an ultrasound endoscope.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092359