K093195

Section 5.0 510(k) Summary

JAN 21 2010

Name:	Cook Ireland Ltd
Address:	O'Halloran Road National Technology Park Limerick, Ireland
Phone:	353 61 334440
Fax:	353 61 334441
Contact Persons:	Emmett Devereux, Quality & Regulatory Manager Jacinta Kilmartin, Regulatory Affairs Specialist
Phone:	353 61 334440
Fax:	353-61-239293
Date:	October 7, 2009
Trade Name:	EchoTip® Ultra Endobronchial High Definition Ultrasound Needle
Common Name:	Aspiration Needle
Classification Name:	Kit, Needle, Biopsy (21 CFR 876.1075, Product Code: FCG)
Predicate Devices:	Olympus Single Use Aspiration Needle NA-201SX-4022 (K050503) Cook Endoscopic Ultrasound Needle (K083330)
Description of the Device:	The EchoTip® Ultra Endobronchial High Definition Ultrasound Needle is an endoscopic ultrasound needle used for fine needle aspiration (FNA). The device is used in conjunction with an endobronchial ultrasound (EBUS) endoscope to gain access to the target site. The needle is dimpled for ultrasonic visualization. The needle is

	advanced into the target site for aspiration. The device allows for the adjustment of the sheath length and the needle length to enable the user to adjust for the working length of the endoscope and to control needle insertion depth. It is preloaded with a stylet which is removed for aspiration. The device is supplied with an adaptor which allows the EchoTip® Ultra Endobronchial High Definition Ultrasound Needle to be connected to the endoscope's accessory channel. The device is also supplied with a syringe that is used to aspirate the specimen.
Indications for use:	This device is used to sample targeted submucosal and extramural lesions within or adjacent to the tracheobronchial tree or gastrointestinal tract through the accessory channel of an ultra sound endoscope for Fine Needle Aspiration (FNA).
Comparison of Characteristics:	The EchoTip® Ultra Endobronchial High Definition Ultrasound Needle is substantially equivalent to the currently marketed predicate devices, the Olympus Single Use Aspiration Needle NA-201SX-4022 (K050503) and Cook Endoscopic Ultrasound Needle (K083330).
Performance Data:	Non-clinical testing was carried out on the device to determine the equivalence of the EchoTip® Ultra Endobronchial High Definition Ultrasound Needle to the predicate devices 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 W-O66-0609
Silver Spring, MD 20993-0002

JAN 21 2010

Ms. Jacinta Kilmartin
Regulatory Affairs Specialist
Cook Ireland Limited
O'Halloran Road
National Technology Park
LIMERICK IRELAND

Re: K093195
Trade/Device Name: EchoTip® Ultra Endobronchial High Definition Ultrasound Needle
Regulation Number: 21 CFR §876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: FCG
Dated: December 22, 2009
Received: December 24, 2009

Dear Ms. Kilmartin:

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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,

for Janine M. Morris, Director (Acting)
Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Section 4.0 Indications for Use

510(k) Number (if known): K093195

Device Name: EchoTip® Ultra Endobronchial High Definition Ultrasound Needle

Indications for Use:

This device is used to sample targeted submucosal and extramural lesions within or adjacent to the tracheobronchial tree or gastrointestinal tract through the accessory channel of an ultra sound endoscope for Fine Needle Aspiration (FNA).

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 K093195