K083330

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COOK ENDOSCOPY
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WWW.COOKMEDICAL.COM

510(k) Summary

FEB - 6 2009

Name:	Cook Endoscopy
Address:	4900 Bethania Station Road Winston-Salem, North Carolina 27105
Phone:	(336)744-0157
Fax:	(336)201-5994
Contact:	Scottie Fariole, Global Regulatory Affairs Specialist
Date:	February 6, 2009
Trade Name:	EchoTip Ultra Ultrasound Needle
Common Name:	Endoscopic Ultrasound Needle
Classification Name:	Kit, Needle, Biopsy (21 CFR 876.1075, Product Code FCG)
Legally Marketed Devices:	Medi-Globe SonoTip II Ultrasound Needle System (K070129) PercuTx Injection/Aspiration Needle Probes with Control Handpiece (K994151) Endoscopic Ultrasound Needle (K934356)
Description of the Device:	The Endoscopic Ultrasound Needle is offered in various needle gauges for injection or aspiration. This device is used in conjunction with an ultrasound endoscope to gain access to the target site. The needle which is dimpled for ultrasonic visualization is advanced into the target site for injection of therapeutic materials or aspiration. The device allows for adjustment of the length of the sheath and needle 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 to aid in inserting the needle which is removed for injection and aspiration. The device is supplied sterile and intended for single use only.
Intended Use:	This device is intended to be used with an ultrasound endoscope for delivery of injectable materials into tissues during endoscopic procedures and fine needle aspirations (FNA) of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the GI tract.

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The expansion of the indications for use is not critical as supported by the Clinical Evidence specifically addressing the expanded target sites and delivery of injectable materials. The evidence discusses the expanded use of the device (or similar design) and the risks associated with that use. The Clinical Evidence supports the substantial equivalence of this device for the new indications for use.

Comparison of Characteristics:	We believe the proposed device to be substantially equivalent to currently marketed predicate devices as cleared by K070129, K994151 and K934356 in terms of Intended Use, Product Description, and Sterility.
Performance Data:	Performance testing performed under simulated use conditions demonstrates that the Endoscopic Ultrasound Needle met the performance requirements of the expanded indications for use. The device will be substantially equivalent to currently cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2009

Mr. Scottie Fariole
Global Regulatory Affairs Specialist
Cook Endoscopy
4900 Bethania Station Road
WINSTON-SALEM NC 27105

Re: K083330
Trade/Device Name: Endoscopic Ultrasound Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: FCG
Dated: November 6, 2008
Received: November 12, 2008

Dear Mr. Fariole:

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 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.

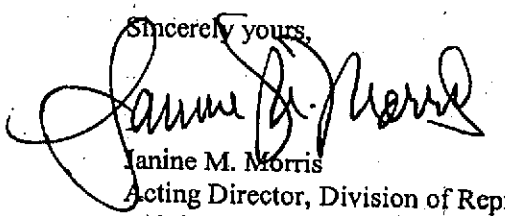
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

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

Indications for Use

510(k) Number (if known): K083330

Device Name: Endoscopic Ultrasound Needle

Indications for Use:

This device is intended to be used with an ultrasound endoscope for delivery of injectable materials into tissues during endoscopic procedures and fine needle aspirations (FNA) of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the GI tract.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K083330