K061937

DEC - 1 2006

ATTACHMENT G : 510(k) Summary

SPONSOR:

Cook Endoscopy
4900 Bethania Station Road
Winston-Salem, NC 27105

CONTACT/SUBMITTER:

Mabel L. Hunter
Global Regulatory Affairs Specialist
[336] -744-0157 Ex.6292

DATE OF SUBMISSION:

July 6, 2006

DEVICE:

Esophageal Dilation Balloon

Trade Name:
Common Name:
Classification:

Cook Endoscopy Esophageal Dilation Balloon
Esophageal Balloon Dilator
Dilator, Esophageal, Class II 78 KNQ
21 CFR § 876.5365

PREDICATE DEVICES:

Wilson-Cook Quantum T.T.C.Dilation Balloon (k935094)
Microvasive RX Biliary Balloon Dilation Catheter (k001338)

INTENDED USE:

Cook Endoscopy's Esophageal Dilation Balloon is intended to endoscopically dilate strictures of the esophagus.

DEVICE DESCRIPTION:

The proposed Cook Endoscopy Dilation Balloon is a single lumen catheter with a balloon mounted on the distal tip. The balloon is inflatable with water to three distinct and progressively larger size diameters to exert force on esophageal strictures resulting in stricture dilation. It is offered in a variety of diameters to accommodate a range of esophageal strictures This device is supplied sterile and intended for single use. This balloon is not sold with inflation device.

COMPARISON OF CHARACTERISTICS:

We believe the proposed device to be substantially equivalent to the named predicates in terms of Intended Use, Indications for Use, performance characteristics tested, balloon diameter and length available and biocompatibility.

PERFORMANCE DATA:

Non-Clinical Testing was performed on characteristics of the balloon with respect to *The FDA Guidance for Urological Balloons* and additional tests as needed to verify safety and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

DEC - 1 2006

Ms. Mabel L. Hunter
Global Regulatory Affairs Specialist
Cook Endoscopy
4900 Bethania Station Road
WINSTON-SALEM NC 27105

Re: K061937
Trade/Device Name: Cook Endoscopy Esophageal Dilation Balloon
Regulation Number: 21 CFR §876.5365
Regulation Name: Esophageal dilator
Regulatory Class: II
Product Code: KNQ
Dated: October 30, 2006
Received: November 1, 2006

Dear Ms. Hunter:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (240) 276-3150
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

K061937

Indications for Use

510(k) Number (if known): K061937

Device Name: Cook Endoscopy Esophageal Dilation Balloon

Indications for Use:

The Esophageal Balloon Dilator is used to endoscopically dilate strictures of the esophagus.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE-IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legan

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061937

Prescription Use Only ✓ OR Over-the-Counter ____
(Per 21 CFR § 801.109