K093236
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510(k) Summary

NOV 1 0 2009

Company Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242

Contact Renee Rowe
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Date Prepared: October 16, 2009

New Device Name

Trade Name: Ethicon Endo Surgery® Optical Dilator

Common or Usual Name: Esophageal Dilator

Classification Name: Esophageal Dilator

Predicate Devices

Ethicon Endo-Surgery® Optical DVS (Dual Vector Shearing) Esophageal Dilator (K031147)

Device Description

The device description is the same as that for the predicate device. The Ethicon Endo-Surgery® Optical Dilator is a sterile, single-use disposable esophageal dilator for use with an endoscope to dilate esophageal strictures under endoscopic visualization. The Optical Dilator is made from a clear flexible polymer. An endoscope having an outer diameter of 10mm or less, such as a standard gastroscope, is positioned within the Optical Dilator to allow for visualization at the stricture site.

Indications for Use

The intended use is the same as that for the predicate device. The Optical Dilator is indicated for dilation of strictures of the esophagus under endoscopic visualization.

Technological Characteristics

The Ethicon Endo-Surgery® Optical Dilator has the same technological characteristics, design, and intended use as the predicate device. The only difference between the new device and the predicate device is that a handle retainer component has been added to secure the handle to the shaft, and the handle material was changed from gray to black. Risk analysis (Failure Mode and Effects and Hazard Analysis) and engineering analyses were used to assess the impact of the modifications.

Performance Data

Bench testing was completed to verify the attachment strength of the handle retainer/handle to the shaft. And, biocompatibility testing was conducted for the new handle and handle retainer materials in accordance with the requirements of ISO 10993-1 and FDA General Program Memorandum #G95-1: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing." Test results demonstrate compliance with ISO 10993-1. A declaration of conformity with Design Controls is included in this submission as required for a Special 510(k). All criteria for success were met.

Risk analysis, engineering analysis, design verification of the attachment strength of the new handle retainer / handle to the shaft, and biocompatibility testing of the new materials indicate that neither the addition of the handle retainer nor the change in the handle material has an impact on the functionality of the device. The fundamental scientific technology and the intended use are the same.

EES believes the new devices are safe and effective and substantially equivalent to the predicate device.

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. Renee Rowe
Staff Project Manager, QS/RA
Ethicon Endo-Surgery, Inc.
a Johnson & Johnson Co.
4545 Creek Road
CINCINNATI OH 45242

NOV 1 0 2009

Re: K093236
Trade/Device Name: Ethicon Endo Surgery® Optical Dilator
Regulation Number: 21 CFR §876.5365
Regulation Name: Esophageal dilator
Regulatory Class: II
Product Code: KNQ
Dated: October 14, 2009
Received: October 15, 2009

Dear Ms. Rowe:

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

Indications for Use

510(k) Number (if known): K093236

Device Name: **Ethicon Endo Surgery® Optical Dilator**

Indications for Use: The Optical Dilator is indicated for dilation of strictures of the esophagus under endoscopic visualization.

Prescription Use ___X___ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K093236