K091322

510(k) Summary

JUN - 1 2009

Company Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, Puerto Rico 00969 USA

Contact Asifa Vonhof
Associate, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242
Phone: (513) 337-3118
FAX: (513) 337-2314
Email: avonhof@its.jnj.com

Date Prepared May 01, 2009

Device Name Trade Name: CONTOUR™ Curved Cutter Stapler and Reloads
Common or Usual Name: Cutter/Stapler and Reloads
Classification Name: Staple, Implantable

Predicate Device K062869 - CONTOUR™ Curved Cutter Stapler and Reloads

Device Description: The CONTOUR™ Curved Cutter Stapler is a multifire, single patient use device with a curved head that cuts and staples. The device delivers four staggered rows of titanium staples, with a knife between the second and third row of staples, and creates a 40 mm curved transection. The device is designed with a feature which prevents closing if a used reload or no reload is in the instrument. Another feature is provided to prevent firing unless the closure trigger is latched in the closed position. A retaining pin holds tissue in place and can be positioned either manually or by squeezing the closure trigger. The instrument may be reloaded five times, for a maximum of six firings per instrument during a single procedure. Each reload cartridge module includes a knife blade with two staggered rows of staples on each side, an anvil, a cutting washer, a retaining pin, and a staple retainer. Reload cartridges are available in two sizes: a blue cartridge for compressed tissue with a thickness of 1.5mm, and a green cartridge for compressed tissue with a thickness of 2.0mm.

Indications for Use: The CONTOUR™ Curved Cutter Stapler is intended for transection, resection, and/or creation of anastomoses. The instrument has application in multiple open or minimally invasive general (gastrointestinal and skeletal muscle), gynecologic, urologic, and thoracic surgical procedures.

Technological Characteristics: The CONTOUR™ Curved Cutter Stapler is identical to the Curved Cutter Stapler marketed device with respect to technological characteristics. There are no material, construction, specification, manufacturing or sterilization process changes to the currently marketed devices. The devices differ only in the labeling (package insert) that has been revised to add contraindications, as well as other clarifications to ensure safer, more effective use of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2009

Ethicon Endo-Surgery, Incorporated
% Asifa Vonhof
Associate, Regulatory Affairs
4545 Creek Road
Cincinnati, Ohio 45242

Re: K091322
Trade/Device Name: CONTOUR™ Curved Cutter Stapler and Reloads
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: II
Product Code: GDW, GAG
Dated: May 1, 2009
Received: May 5, 2009

Dear Asifa Vonhof:

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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091322

Device Name: CONTOUR™ Curved Cutter Stapler and Reloads

Indications for Use:

The CONTOUR™ Curved Cutter Stapler is intended for transection, resection, and/or creation of anastomoses. The instrument has application in multiple open or minimally invasive general (gastrointestinal and skeletal muscle), gynecologic, urologic, and thoracic surgical procedures.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091322