K040038

FEB - 4 2004

Curved Cutter Stapler and Reloads
510(k) Summary of Safety and Effectiveness

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

Contact
Katie Fordyce
Regulatory Affairs Associate II

Date Prepared:
January 8, 2004

Name of Device
Trade Name: Curved Cutter Stapler
Classification Name: Staple, Implantable

Predicate Devices:
PROXIMATE ACCESS 55 Articulating Linear Stapler, cleared under K932434 on 02/07/94.
PROXIMATE Linear Cutter, cleared under K843034 on 09/17/84.

Device Description
The Curved Cutter Stapler is a sterile, single use device with a curved head that cuts and staples. It delivers four staggered rows of titanium staples, two rows on each side of a cut line. The device is supplied with one cartridge and can be reloaded for a total of six (6) firings. The reloads will be 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.

Intended Use
The Curved Cutter Stapler is intended for use in gastrointestinal surgical procedures for transection and resection of tissues.

Technological Characteristics
The Curved Cutter Stapler is similar to the predicate devices in that it has the same intended use and is a single use sterile device. The Curved Cutter Stapler is different from the predicate devices in that it produces a curved staple line.

Performance Data
Bench and pre-clinical testing was performed to demonstrate that the device performs as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 2004

Ms. Katie Fordyce, MBA
Regulatory Affairs Associate II
Ethicon Endo-Surgery, Inc.
4545Creek Road
Cincinnati, Ohio 45242-2839

Re: K040038
Trade/Device Name: Curved Cutter Stapler
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: January 8, 2004
Received: January 8, 2004

Dear Ms. Fordyce:

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 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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K040038

Device Name: Curved Cutter Stapler

Indications for Use:

The Curved Cutter Stapler is intended for use in gastrointestinal surgical procedures for transection and resection of tissues.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

K040038