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LIGACLIP® 5 M/L
510(k) Summary of Safety and Effectiveness

MAR 1 4 2005

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

Contact
Kimberly Shoemaker
Manager, Regulatory Affairs

Date Prepared:
February 10, 2005

Name of Device
Trade Name: LIGACLIP® 5M/L Endoscopic Multiple Clip Applier
Classification Name: Implantable Clip

Predicate Devices:
Trade Name: LIGACLIP® ERCA Endoscopic Rotating Multiple Clip Applier
Cleared under 510(k) numbers K0864102 on November 5, 1986. The Titanium Clips used with the applier were cleared March 9, 1983 under K830503.

Device Description
The LIGACLIP® 5 M/L Endoscopic Multiple Clip Applier is a sterile, single patient use, disposable surgical instrument designed to provide a means of ligation through an appropriately sized trocar. The instrument configuration consists of a pistol grip handle, an actuation trigger, a rotation knob, a shaft having an outer diameter of 5.5mm and a length of 33cm. At the distal end of the shaft is a set of jaws for forming ligating clips. The device contains 15 clips.

Indications for Use
The LIGACLIP® 5 M/L 5 mm Endoscopic Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated. The tissue being ligated should be consistent with the size of the clip.

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Technological Characteristics

The LIGACLIP® 5 M/L 5 mm Endoscopic Multiple Clip Applier is identical to the predicate device with respect to intended use. The device is operated in a manner similar to the predicate device.

Performance Data

Bench testing was performed to ensure that the device performs as intended. All testing results demonstrated satisfactory performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2005

Ms. Kimberly Shoemaker
Manager, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K050344
Trade/Device Name: LIGACLIP® 5M/L 5mm Endoscopic Multiple Clip Applier
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: FZP
Dated: February 10, 2005
Received: February 11, 2005

Dear Mr. Shoemaker:

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company
4545 CREEK ROAD
CINCINNATI, OHIO 45242-2839

Indications for Use

510(k) Number (if known): K050344

Device Name: LIGACLIP® 5 M/L 5 mm Endoscopic Multiple Clip Applier

Indications for Use:

The LIGACLIP® 5 M/L 5 mm Endoscopic Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated.

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)

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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050344