JUN - 4 2003

K030824

LAP DISC Hand Access Device
510(k) Summary of Safety and Effectiveness

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

Contact
Elizabeth Miller
Regulatory Affairs Associate I

Date Prepared:
March 13, 2003

Name of Device
Trade Name: LAP DISC Hand Access Device
Classification Name: Laparoscope, General & Plastic Surgery

Predicate Devices:
LAP DISC Hand Access Device, cleared under K010870 on 06/18/01 and K020307 on 4/26/02

Device Description
The LAP DISC is a sterile, single-use disposable device. The LAP DISC is an abdominal wall closure unit consisting of three overlaid plastic rings that are interconnected by means of a silicone rubber membrane. The two lower rings hold the abdominal wall to maintain peritoneal gas pressure. The bottom ring is a flexible ring made with a shape-memory alloy. The top ring has a structure similar to the aperture in a camera (an Iris Valve). Because the aperture of the Iris Valve can be adjusted continuously, the system can maintain constant peritoneal gas pressure while allowing the insertion of the surgeon's hand and alternatively, it can be used as an insertion site.

Intended Use
The LAP DISC Hand Access Device is intended to provide extracorporeal extension of pneumoperitoneum and abdominal access for the surgeon during laparoscopic surgery. The LAP DISC is indicated for use in laparoscopic procedures, where entry of the surgeon's hand may facilitate the procedure, and for extraction of large specimens. The LAP DISC has application in colorectal, urological, gynecologic and general surgical procedures. This indication for use includes the specific procedures which fall under these broad categories.

Technological Characteristics

The LAP DISC Hand Access Device technological characteristics of the new device are the same as the predicate device. No changes (materials construction, specifications, manufacturing or sterilization processes) to the currently marketed device. The device differs only in the indications and the addition of the measuring tape accessory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Elizabeth Miller
Regulatory Affairs Associate I
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K030824
Trade/Device Name: LAP DISC Hand Access Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: March 13, 2003
Received: March 14, 2003

Dear Ms. Miller:

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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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): K030824

Device Name: LAP DISC Hand Access Device

Indications for Use:

The LAP DISC Hand Access Device is intended to provide extracorporeal extension of pneumoperitoneum and abdominal access for the surgeon during laparoscopic surgery. The LAP DISC is indicated for use in laparoscopic procedures, where entry of the surgeon's hand may facilitate the procedure, and for extraction of large specimens. The LAP DISC has application in colorectal, urological, gynecologic and general surgical procedures. This indication for use includes the specific procedures which fall under these broad categories.

Miriam C. Provost

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

510(k) Number K030824

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)