ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

K994280

MAR 17 2000

4545 CREEK ROAD
CINCINNATI, OH 45242-2839

SUMMARY OF SAFETY AND EFFECTIVENESS

COMPANY:

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

CONTACT:

Ruth Ann Wood
Senior Regulatory Affairs Associate
Telephone: 513/337-3468
FAX: 513/337-8539

DATE PREPARED:

December 17, 1999

NAME OF THE DEVICE and CLASSIFICATION:

Trade Name: UltraCision Harmonic Scalpel Sharp Curved Blade
Classification: LFL

PREDICATE DEVICES:

UltraCision Harmonic Scalpel Curved Blades, Sharp Hook Blades and Dissecting Hook Blades

DEVICE DESCRIPTION:

The UltraCision instruments are hand-held instruments which cut and coagulate soft tissue when attached to the ultrasonic hand piece and generator.

INTENDED USE:

These instruments are indicated for soft tissue indications when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, gynecologic, and thoracic surgery.

TECHNOLOGICAL CHARACTERIZATION:

The technological characteristics of the Sharp Curved Blade are the same as the predicate devices. Ultrasonic technology is the method of activation. The Sharp Curved blades are constructed wholly of biocompatible materials which are in compliance with ISO 10993-1 for the intended contact profile.

PERFORMANCE DATA:

Preclinical testing was performed to ensure that the devices perform as intended. All bench and animal studies demonstrated satisfactory performance in cutting and coagulation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2000

Ms. Ruth Ann Wood
Senior Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242-2839

Re: K994280
Trade Name: UltraCision® Harmonic Scalpel® Sharp Curved Blade
Regulatory Class: II
Product Code: LFL
Dated: December 17, 1999
Received: December 20, 1999

Dear Ms. Wood:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

510(k) NUMBER (IF KNOWN): K994280

DEVICE NAME: _____

INDICATIONS FOR USE:

The UltraCision Instruments are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, gynecologic, and thoracic surgery.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994280

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

Concurrence of CDRH, Office of Device Evaluation (ODE

Prescription Use X OR Over-The-Counter
(Per 21 CFR 801.109) (Optional Form