SEP 17 1999

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

K990362

4545 CREEK ROAD
CINCINNATI, OH 45242-2839

SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter: Ethicon Endo-Surgery, Inc
4545 Creek Road
Cincinnati, Ohio 45242

Contact: Ruth Ann Wood

Date: February 5, 1999

Device Name: Ultracision Harmonic Scalpel

Predicate Devices: Ultracision Harmonic Scalpel K983316, K941897, K924281
Valley Labs Electrocautery Pencils K955109, K962044, K964602
Colorado Microdissection Needle K881763
Arthrocare Electrosurgery System K971532

Device Description: The Ultracision Harmonic Scalpel is a cutting and coagulating surgical instrument. The device system has three essential parts: the generator/footswitch, the hand piece, and the blades. The blades are offered in a variety of configurations, shapes and sizes.

Intended Use/Indications for Use:
The Harmonic Scalpel is intended to cut and coagulate soft tissues. It is to be used when bleeding control and minimal thermal injury is desired. These instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, gynecologic, ENT (Ears, Nose,Throat), thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

Technological Characteristics:
The technological characteristics of the Ultracision Harmonic Scalpel are the same as the predicate

devices. Ultrasonic technology is the method of activation. The Harmonic Scalpel is constructed wholly of biocompatible materials which are in compliance with ISO 10993-1 for their intended patient contact profile.

Performance Data:

Preclinical testing was performed to ensure the device performs 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

SEP 17 1999

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

Re: K990362
Trade Name: Ultracision Harmonic Scalpel
Regulatory Class: II
Product Code: LFL, GEI
Dated: June 25, 1999
Received: June 28, 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 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 (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) 594-4595. 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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): K990362

DEVICE NAME: Ultracision Harmonic Scalpel

INDICATIONS FOR USE:

The Harmonic Scalpel is intended to cut and coagulate soft tissues. It is to be used when bleeding control and minimal thermal injury is desired. These instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, gynecologic, ENT (Ears, Nose, Throat), thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990362