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

4545 CREEK ROAD
CINCINNATI, OH 45242-2839

MAY 31 2001

K010898

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: 513/337-2468

DATE PREPARED:
March 23, 2001

NAME OF THE DEVICE:
UltraCision® Harmonic Scalpel® Blades with Protective Sleeve
Classification LFL

PREDICATE DEVICE:
UltraCision® Harmonic Scalpel® Blades

DEVICE DESCRIPTION:
The protective sleeve is a cylindrical shaped silicone tube applied by the user to the blade sheath before a surgical procedure. The purpose of the protective sleeve is to provide a thermal barrier between the blade sheath and the patient.

INTENDED USE:
The UltraCision Harmonic Scalpel is 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, gynecological ENT (Ears, Nose, Throat), thoracic surgery including mobilization of the Internal Mammary Artery (IMA).

TECHNOLOGICAL CHARACTERIZATION:
The UltraCision Harmonic Scalpel is a medical device that uses ultrasonic energy to cause mechanical vibrations to cut and coagulate soft tissues.

PERFORMANCE DATA:

Bench testing and preclinical testing were performed to ensure that the device performs as intended. All testing demonstrated satisfactory performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2001

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

Re: K010898
Trade/Device Name: UltraCision® Harmonic Scalpel Blades with Protective Sleeve
Regulatory Class: II
Product Code: LFL
Dated: March 23, 2001
Received: March 26, 2001

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 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). 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 requirements, 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

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): K 010898

DEVICE NAME: Ultracision Harmonic Scalpel Blades with Protective Sleeves

INDICATIONS FOR USE:

The Harmonic Scalpel is 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 scalpel in general, gynecologic, ENT (Ears, Nose Throat) and thoracic surgery, including mobilization of Internal Mammary Artery (IMA).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010898