OCT 21 1998

K 983316

Appendix A: 510(k) Summary of Safety and Effectiveness

Statement	Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR §807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.
Device description	The UltraCision® 5mm Instruments as described in this special premarket notification are hand held instruments available in a 10cm, 14cm, and 32cm Curved Blade configuration and a 10cm and 14cm Sharp or Dissecting Hook Blade configuration. An optional blade grip is included in the 14cm configurations. When attached to the ultrasonic hand piece and generator, ultrasonic activation of the blade allows the instrument to cut and coagulate tissue. The UltraCision 5mm Instruments are ultrasonic cutting and coagulation devices and have been classified by FDA as Class II devices with a product code designation of LFL.
Intended use	The UltraCision 5mm Instruments are intended for the cutting and coagulation of soft tissues.
Indications statement	The UltraCision 5mm 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, including mobilization of the Internal Mammary Artery (IMA).
Technological characteristics	The technological characteristics of the UltraCision® 5mm Instruments are the same as the predicate devices. Ultrasonic technology is the method of activation.

Continued on next page

Appendix A: 510(k) Summary of Safety and Effectiveness,
Continued

Performance data	Preclinical testing was performed to ensure the device performs as intended. All studies demonstrated satisfactory performance in the areas of cutting, coagulation, access, visibility, blunt and fine dissection, and ease of use.
Contact	Chuck Tabri Ethicon Endo-Surgery, Inc. 4545 Creek Road Cincinnati, Ohio 45242
Date	September 18, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 1998

Mr. Chuck Tabri
Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242-2839

Re: K983316
Trade Name: UltraCision® 5mm Instrument
Regulatory Class: II
Product Code: LFL
Dated: September 18, 1998
Received: September 21, 1998

Dear Mr. Tabri:

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.

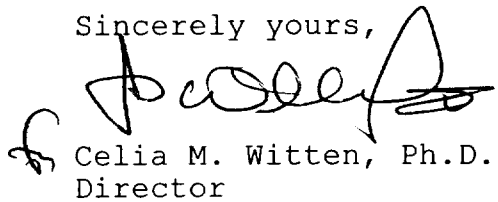
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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) 594-4659. 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 (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

Appendix B: Indications for Use Statement

Statement

Indications for Use Statement:

510(k) Number: K 983316

Device Name: UltraCision® 5mm Instrument

Indications for Use: The UltraCision 5mm 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, including mobilization of the Internal Mammary Artery (IMA).

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983316