

K 980099

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

APR - 9 1998

Submitter	Ethicon Endo-Surgery, Inc. 4545 Creek Road Cincinnati, Ohio 45242
Contact	Larry Carrier
Date prepared	January 9, 1998
Name of Device	Classification Name: Electrosurgical cutting and coagulation device and accessories; Common Name: Ultrasonic cutting and coagulation device and accessories; <u>Trade Name/ Proprietary Name</u> :UltraCision® LaparoSonic Coagulating Shears (LCS-5 (LCSK5 and LCSB5)).
Predicate devices	Ethicon Endo-Surgery's UltraCision LaparoSonic Coagulating Shears - K925699; United States Surgical Corporation's ULTRASHEARS - K971861
Device description	The UltraCision® LCS-5 are hand held shear instruments which cut and coagulate tissue when attached to the ultrasonic hand piece and generator.
Intended use	The UltraCision® LCS-5 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 scalpels in abdominal, pediatric, gynecologic and other endoscopic procedures.
Technological characteristics	The technological characteristics of the LCS-5 are the same as the predicate devices. Ultrasonic technology is the method of activation. The LCS-5 are 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 1998

Mr. Larry Carrier
Project Manager, Regulatory Affairs
Ethicon Endo-Surgery, Incorporated
4545 Creek Road
Cincinnati, Ohio 45242

Re: K980099
Trade Name: UltraCision LaparoSonic Coagulating Shears
(LCSK5 and LCSB5)
Regulatory Class: II
Product Code: LFL
Dated: January 9, 1998
Received: January 12, 1998

Dear Mr. Carrier:

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.

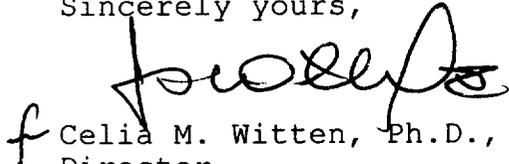
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,


f 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

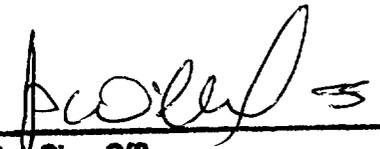
Indications for Use Statement:

510(k) Number: K 9800 99

Device Name: UltraCision® LCS-5

Indications for Use: The UltraCision® LCS-5 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 scalpels in abdominal, pediatric, gynecologic and other endoscopic procedures.

Prescription Use _____
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980099