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

K 971302 JUL - 7 1997

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 LaparoSonic® Hook Blade instruments are two styles of sterile, single patient use instruments consisting of a titanium blade with a non-removable sheath. The two styles consist of a Sharp Hook and Dissecting Hook. The working lengths are approximately 32 cm. The UltraCision HS2 Blade is a sharp hook and has a working length of approximately 10 cm. The system consists of a blade affixed with a sheath, a hand piece, blade adaptor, blade wrench, generator, foot switch and cart.
Intended use	The intended use for the New Device is the same as that of the Predicate Device in that it is intended for cutting soft tissue and providing hemostasis in general and thoracic surgery.
Indications statement	The UltraCision 5mm LaparoSonic® Hook Blades and UltraCision HS2 Blade 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 and thoracic surgery, including the mobilization of the Internal Mammary Artery (IMA).

Continued on next page

510(k) Summary of Safety and Effectiveness, Continued

Technological characteristics	The technological characteristics of the New Devices are the same as the Predicate Device. The same ultrasonic characteristics remain as a method of activation.
Performance data	Pre-clinical laboratory evaluations were performed to ensure that the device can be used as designed. The studies demonstrated acceptable performance in cutting, blunt tissue dissection and coagulation in the mobilization of the IMA.
Conclusion	**Based on the 510(k) summaries and 510(k) statements (21 CFR §807) and the information provided herein, we conclude that the New Devices are substantially equivalent to the Predicate Device under the Federal Food, Drug and Cosmetic Act.**
Contact	Lonnie Pace Ethicon Endo-Surgery, Inc. 4545 Creek Road Cincinnati, Ohio 45242 Work phone (513) 786-7141 FAX number (513)786-7134
Date	April 4, 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Lonnie Pace
Project Manager
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242-2839

JUL - 7 1997

Re: K971302
UltraCision™ 5mm Hard Sheath LaparoSonic®
Hook Blades and UltraCision™ HS2 Blade
Regulatory Class: Unclassified
Product Code: LFL
Dated: April 4, 1997
Received: April 8, 1997

Dear Mr. Pace:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined these devices are 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 devices, 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.

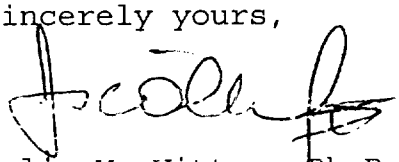
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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

Indications for Use Statement

Statement

The following is the indication for Use Statement:

510(k) Number K_971302
Device Name UltraCision 5mm Hard Sheath LaparoSonic® Blade and UltraCision HS2 Blade

Indications for Use

The UltraCision 5mm LaparoSonic® Hook Blades and UltraCision HS2 Blade 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 and thoracic surgery, including the mobilization of the Internal Mammary Artery (IMA).

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971302

Prescription Use X
(Per 21 CFR 801.109)