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ATTACHMENT V

510(k) SUMMARY

K031847

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.

MODIFIED DEVICE NAME:	CardioVations Retractor
PREDICATE DEVICE NAME:	CardioVations Ultra-Retractor

Device Description

The CardioVations Retractor is a single patient use device for dissection and retraction of soft tissue to maintain space while under endoscope visualization. For example, like the predicate device, the retractor will be used to dissect and retract tissue surrounding a vessel to allow for instrument passage beneath the shaft of the retractor in vessel harvesting procedures. The blunt, spoon (hood) distal tip functions to dissect and create a working cavity for instrument passage. The wide shaft provides for retraction and maintenance of the operative working space. The transparent tip allows visualization during insertion, tunneling and dissection. A vein retractor feature has been added. The device is compatible with the CardioVations Optical Bipolar Device (included in the vessel harvesting package tray).

Intended Use

The CardioVations Retractor has application for use in the creation and maintenance of an operative cavity in the extraperitoneal spaces such as the retroperitoneal, preperitoneal, and subcutaneous areas. The device may be used in surgical procedures requiring dissection and retraction of tissue.

Indications Statement	The CardioVations Retractor has application for use in the creation and maintenance of an operative cavity in the extraperitoneal spaces such as the retroperitoneal, preperitoneal and subcutaneous areas. The device may be used in surgical procedures requiring dissection and retraction of tissue.
Technological Characteristics	The modified device has the same technological characteristics as the predicate device. The form, fit, function and method of operation are similar.
Performance Data	Results of verification testing indicates that the product meets the established performance requirements.
Conclusion	Based upon the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the subject device is substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.
Contact	Peter Cecchini Manager Regulatory Affairs ETHICON, Inc. Rt. 22 West Somerville, NJ 08876-0151
Date	June 13, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 1 2003

Mr. Peter Cecchini
Manager, Regulatory Affairs
Ethicon, Inc.
Route 22 West
Somerville, New Jersey 08876-0151

Re: K031847
Trade/Device Name: CardioVations Retractor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: June 13, 2003
Received: June 26, 2003

Dear Mr. Cecchini :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), 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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Miriam C. Provost

for 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

INDICATIONS FOR USE

510(k) Number (if known): K031847

Device Name: CardioVations Retractor

Indications for Use: The CardioVations Retractor has application for use in the creation and maintenance of an operative cavity in the extraperitoneal spaces such as the retroperitoneal, preperitoneal and subcutaneous areas. The device may be used in surgical procedures requiring dissection and retraction of tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER 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 1-2-9G)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices