

**SUMMARY OF SAFETY AND EFFECTIVENESS**

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**510(k) Summary of  
Safety and Effectiveness**

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:** PowerStar Bipolar Scissors

**EXISTING (legally marketed)**

**DEVICE NAME:** PowerStar Bipolar Scissors

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**510(K) SUMMARY**

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**Device Description**

The PowerStar Bipolar Scissors are limited-life reusable instruments available in various standard sizes and shapes similar to conventional surgical scissors. These scissors can be connected to the bipolar output mode on electrosurgical generators to facilitate dissection, transection, and bipolar coagulation.

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**Intended Use**

The intended use of the PowerStar Bipolar Scissor is to cut and coagulate soft tissue in open surgical procedures.

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SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

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**Indications  
Statement**

The PowerStar Bipolar Scissors are non-sterile, reusable devices intended to facilitate cutting and bipolar coagulation of soft tissue in open surgical procedures such as general, gynecological, oncologic, vascular, plastic, thoracic, ear, nose and throat, urological, and cardiovascular surgeries.

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**Technological  
Characteristics**

The modified device is technologically the same as the existing device.

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**Performance Data**

Preclinical laboratory and clinical evaluations were performed to ensure that the device functions as intended. Sufficient data have been gathered from preclinical and clinical testing to assess that the device performs as clinically intended.

Sufficient data has been gathered from pre-clinical and clinical testing to assess the safety and effectiveness characteristics of the modified device.

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**Conclusions**

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the modified device is substantially equivalent to the existing legally marketed device under the Federal Food, Drug and Cosmetic Act.

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**Contact**

Gregory R. Jones  
Director  
Regulatory Affairs  
ETHICON, Inc.  
Rt. #22 West  
Somerville, NJ 08876-0151

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**Date**

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PowerStar Bipolar Scissors  
ETHICON, Inc.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Gregory R. Jones  
Director  
Regulatory Affairs  
Ethicon, Inc.  
PO Box 151  
Somerville, New Jersey 08876-0151

OCT 29 1997

Re: K973173  
Trade Name: PowerStar Bipolar Scissors and Accessories  
Regulatory Class: II  
Product Code: GEI  
Dated: August 20, 1997  
Received: August 25, 1997

Dear Mr. Jones:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the 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 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 devices in the Federal Register. Please note: this response to your premarket notification submissions

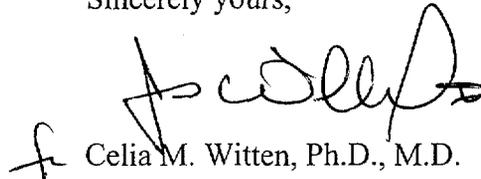
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does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 a legally marketed predicate device 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and a long horizontal stroke at the end.

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

INDICATION FOR USE

K973173

510(k) Number (if known):

Device Name:

PowerStar Bipolar Scissors

Indications for Use:

"The PowerStar Bipolar Scissors are non-sterile, reusable devices intended to facilitate cutting and bipolar coagulation of soft tissue in open surgical procedures such as general, gynecological, oncologic, vascular, plastic, thoracic, ear, nose and throat, urological, and cardiovascular surgeries".

Surgical procedures would include the following:

General Surgery

Bowel  
Breast Biopsies  
Hernia Repair  
Lysis of Adhesions  
Upper GI  
GI (other)  
Cholecystectomy  
Thyroid  
Splenectomy

Oncological Surgery

Mastectomy  
Axillary Node Dissection

Plastic Surgery

Mammoplasty  
Blepharoplasty  
Rhytidectomy  
Panniculectomy  
Forearm  
Pedicle Flap  
Facial

OB/GYN Surgery

Hysterectomy  
Salpingo-oophrectomy  
Myomectomy  
Endometriosis  
Ovariohysterectomy

Urological Surgery

Nephrectomy  
Prostatectomy  
Cystotomy

Ear, Nose & Throat Surgery

Neck Mass  
Mastoidectomy  
Tympanoplasty  
Tonsillectomy

Cardiovascular/Thoracic Surgery

Femoral Popliteal Bypass  
Internal Mammary Artery (IMA)  
Harvesting  
Pericardial Window  
Biopsy of the Thymus

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The Counter Use \_\_\_\_\_

(Optional Format 1-2-9G)

(Division Sign-Off)

Division of General Restorative Devices

PowerStar Bipolar Scissors  
ETHICON, Inc.

510(k) Number

K973173