

10981361

SECTION 7

JUL 13 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

**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

510(K) SUMMARY

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.

Intended Use

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

Continued on next page

PowerStar Bipolar Scissors
ETHICON, Inc.

SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

**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.

**Technological
Characteristics**

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

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.

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.

Contact

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

Date

PowerStar Bipolar Scissors
ETHICON, Inc.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 1998

Mr. Gregory R. Jones
Director
Regulatory Affairs
Ethicon, Inc.
A Johnson & Johnson Company
P.O. Box 151
Somerville, New Jersey 08876

Re: K981361
Trade Name: PowerStar Bipolar Scissors
Regulatory Class: II
Product Code: GEI
Dated: April 10, 1998
Received: April 14, 1998

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.

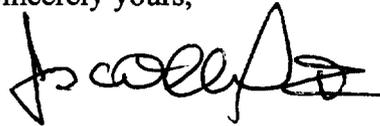
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification

submissions 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) 594-4648. 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

K981361

INDICATION FOR USE

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, among others, 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

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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)

PowerStar Bipolar Scissors
ETHICON, Inc.


 (Division of ~~General~~ **Medical** ~~Restorative~~ **Devices**)
 Division of **General Restorative Devices**
 510(k) Number K981361