

OCT - 7 1997

**510(k) SUMMARY**  
**BIPOLAR SCISSORS WITH ENABLE BIPOLAR DISPOSABLE CARTRIDGES**  
**510(k) NOTIFICATION K 972558**

**GENERAL INFORMATION**

**Manufacturer:** ENABLE Medical Corporation  
6345 Centre Park Drive  
West Chester, OH 45069-3863  
(513) 755-7600  
(513) 755-7676  
Est. Reg. No. 1530251

**Contact Person:** Michael D. Hooven  
President/CEO  
ENABLE Medical Corporation

**Date Prepared:** -----

**DEVICE DESCRIPTION**

**Classification:** Class II

**Trade Name:** ENABLE Bipolar Scissors with ENABLE Bipolar Disposable Cartridges

**Generic/Common Name:** Electrosurgical cutting and coagulation device and accessories  
21CFR878.4400

**PREDICATED DEVICES**

1. Symbiosis Bipolar Scissors (K951387)
2. Everest Medical Bipolar Scissors (K945975 and K955001)
3. CardioThoracic Systems MIDCAB/SVH Bipolar Scissors (K963930)
4. Ethicon PowerStar Bipolar Scissors (K960476)

**INTENDED USE**

The ENABLE Bipolar Scissors with ENABLE Bipolar Disposable Cartridges are intended to cut tissue and control bleeding through coagulation during general surgery.

**PRODUCT DESCRIPTION**

The ENABLE Bipolar Scissors is a reusable electrosurgical instrument consisting of an instrument handle with a pair of scissors blades which attaches to the ENABLE Bipolar Disposable Cartridges and an electrosurgical generator. Electric current flows from the electrodes in the cartridges to the stainless steel cutting surfaces of the blades. The electrosurgical generator controls the flow of the electric current down the electrode. The overall length of the device is between 4 and 11 inches. The power cord connecting the handle to the power control unit is approximately 120 inches. The blades are between 1 and 2 inches in length.

The surgeon places the opened scissors across the tissue to be cut and closes the scissors handle while moving the scissors across the tissue. Energizing the electrosurgical generator via the generator's footswitch, the surgeon can simultaneously cut and coagulate the target tissue. The surgeon can vary the current flow rate according to the tissue and the amount of bleeding encountered. The power setting for the ENABLE Bipolar Scissors is 20-30 watts.

The ENABLE Bipolar Scissors with ENABLE Bipolar Disposable Cartridges are substantially equivalent to the above-identified predicate devices with regard to intended use, function, physical characteristics, materials and sterilization method. ENABLE, CardioThoracic, Symbiosis, Everest and Ethicon devices are all bipolar scissors that cut tissue and coagulate soft tissue through the use of bipolar technology. All the bipolar scissors are connected to the same or similar electrosurgical generators and use similar power ranges for operation.

**SUMMARY**

As contained in this 510(k) summary, the ENABLE Bipolar Scissors with ENABLE Bipolar Disposable Cartridges are substantially equivalent to the predicate devices identified.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Michael D. Hooven  
President  
ENABLE Medical Corporation  
6345 Centre Park Drive  
West Chester, Ohio 45069-3863

OCT - 7 1997

Re: K972558  
ENABLE Bipolar Scissors with  
ENABLE Disposable Cartridges  
Regulatory Class: II  
Product Code: GEI  
Dated: July 7, 1997  
Received: July 9, 1997

Dear Mr. Hooven:

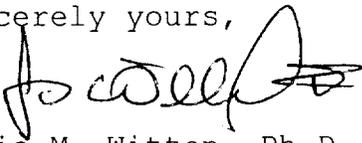
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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 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,



fm

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

K972558

**Bipolar Scissors  
510(k) Premarket Notification**

**STATEMENT OF INDICATIONS OF USE**

The ENABLE Bipolar Scissors with ENABLE Bipolar Disposable Cartridges is intended to cut tissue and control bleeding through coagulation during general surgery.

Prescription Use X  
(Per 21 CFR 801.109)

  
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(Division Sign-Off)  
Division of **General Restorative Devices**  
510(k) Number K972558