JUN 29 1998

510(k) SUMMARY
OSCAR™ BIPOLAR SCISSORS WITH OSCAR™ BIPOLAR DISPOSABLE CARTRIDGES
510(k) NOTIFICATION K 981219

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:

Mark L. Friedman, PhD
Directory, Quality Assurance/Regulatory Affairs
ENABLE Medical Corporation

Date Prepared:

DEVICE DESCRIPTION

Classification:

Class II

Trade Name:

OSCAR™ Bipolar Scissors with OSCAR™ 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 and K973173)
5. ENABLE Bipolar Scissors (K972558)

INTENDED USE

The OSCAR™ Bipolar Scissors with OSCAR™ Bipolar Disposable Cartridges are intended to cut tissue and control bleeding through coagulation during open surgical procedures and in general surgery.

PRODUCT DESCRIPTION

The OSCAR™ Bipolar Scissors is a reusable electrosurgical instrument consisting of an instrument handle with a pair of scissors blades which attaches to the OSCAR™ Bipolar Disposable Cartridges and an electrosurgical generator. Electric current flows between the electrodes in the cartridges and 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 OSCAR™ Bipolar Scissors is 20-30 watts.

The OSCAR™ Bipolar Scissors with OSCAR™ 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 OSCAR™ Bipolar Scissors with OSCAR™ Bipolar Disposable Cartridges are substantially equivalent to the predicate devices identified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 1998

Mark L. Friedman, Ph.D.
Director Quality Assurance and Regulatory Affairs
Enable Medical Corporation
6345 Centre Park Drive
West Chester, Ohio 45069-3863

Re: K981219
Trade Name: Oscar Bipolar Scissors and Oscar Bipolar Reusable Cartridges
Regulatory Class: II
Product Code: GEI
Dated: March 27, 1998
Received: April 3, 1998

Dear Dr. Friedman:

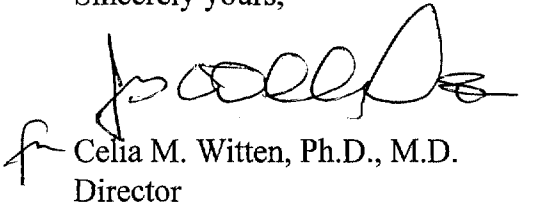
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date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

OSCAR™ Bipolar Scissors
510(k) Premarket Notification

STATEMENT OF INDICATIONS OF USE

The OSCAR™ Bipolar Scissors with OSCAR™ Bipolar Disposable Cartridges is intended to cut tissue and control bleeding through coagulation during open surgical procedures and in general surgery.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981219