510(k) SUMMARY
ENABLE ENDOSCOPIC BIPOLAR SCISSORS
510(k) NOTIFICATION K 992996

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. Ph.D.
Vice President of Quality Assurance & Regulatory Affairs
ENABLE Medical Corporation

Date Prepared:

[to be added after 510(k) process]

DEVICE DESCRIPTION

Classification:

Class II

Trade Name:

ENABLE Endoscopic Bipolar Scissors

Generic/Common Name:

Electrosurgical cutting and coagulation device and accessories
21CFR878.4400

PREDICATED DEVICES

1. Symbiosis Bipolar Scissors (K950286 and K951387)
2. Everest Medical Bipolar Scissors (K945975 and K955001)
3. CardioThoracic Systems MIDCAB/SVH Bipolar Scissors (K963930)
4. ENABLE Medical Corporation Bipolar Scissors (K972558 and K981219)

INTENDED USE

The ENABLE Endoscopic Bipolar Scissors intended use is substantially equivalent to the intended use statements of CardioThoracic, Symbiosis, Everest and ENABLE Bipolar Scissors. ll bipolar scissors described in this section cut and coagulate soft tissue through the use of .polar technology. The ENABLE Endoscopic Bipolar Scissors are intended for use during laparoscopic and general surgical procedures.

PRODUCT DESCRIPTION

The ENABLE Endoscopic Bipolar Scissors are substantially equivalent to the CardioThoracic Systems, Symbiosis, Everest Medical and ENABLE Bipolar Scissors in that each consist of a handle which is connected to a pair of scissor blades with electrodes on each blade. All the devices utilize the same bipolar electrosurgical technology, i.e., radio frequency (RF) energy, to cauterize the blood vessels by heating proteins in the tissue to a temperature where the proteins congeal.

The ENABLE Endoscopic Bipolar Scissors contain both a negative and positive electrode on each blade. The function of the ENABLE and predicate devices is the same; current flows from a negatively charged pole through the tissue to a positively charged pole. The ENABLE, CardioThoracic, Symbiosis and Everest Bipolar Scissors are connected to a similar electrosurgical generator that supplies RF bipolar energy. The ENABLE, CardioThoracic and Everest Bipolar Scissors are all labeled for use with the Valleylab Force 2 Electrosurgical Generator or equivalent electrosurgical units. All four bipolar scissors listed in this notification are labeled for operation at a comparable range (15-35 watts). Labeling for the ENABLE Endoscopic Bipolar Scissors are provided with each product. As with other bipolar instruments, there is no need for a grounding pad for the return electrode, therefore, the current does not travel through the patient to the grounding pad as it does with monopolar instruments. Patient burns seen with monopolar devices due to electrical current passage are eliminated.

The ENABLE Endoscopic Bipolar Scissors and the listed predicate devices are of similar size with an overall length range of 33 to 48cm (13 to 19 inches) and a scissors blade length range of approximately 0.7 inches. The scissors shaft is designed to fit a standard 5mm cannula. The bipolar devices utilize similar materials of construction including stainless steel scissors blades. All of the materials utilized in the ENABLE Endoscopic Bipolar Scissors are standard medical device materials that are used in a variety of tissue contact medical devices.

The ENABLE Endoscopic Bipolar Scissors will meet the following industrial/international standards.

ISO 10993/EN 30993	Biological Evaluation of Medical Devices
ISO 11607	Packaging for Terminally Sterilized Medical Devices
ISO 11137	Sterilization of Health Care Products, Sterilization of Gamma Irradiation
ANSI/AAMI HF18	Electrosurgical Devices
IEC 60601-2-2/EN 60601-2-2	Medical Electrical Equipment: Particular Requirements for Safety of High Frequency Surgical Equipment
ASTM F1079	Standard Specification for Insert and Non-insert Surgical Scissors

SUMMARY

As contained in this 510(k) summary, the ENABLE Endoscopic Bipolar Scissors 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

NOV 24 1999

Mark L. Friedman, Ph.D.
Vice President of Quality Assurance and
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Enable Medical Corporation
6345 Centre Park Drive
West Chester, Ohio 45069

Re: K992996
Trade Name: Endoscope Bipolar Scissors
Regulatory Class: II
Product Code: GEI
Dated: August 31, 1999
Received: September 7, 1999

Dear Dr. Friedman:

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 (Premarket 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.

510(k) Number: K992994
Device Name: The Turbo 7000™ System

Intended Use:

The Turbo 7000™ System's intended use is the cutting and removal of bone and tissue in general ENT, head & neck, and otoneurologic procedures.

Otology procedures would include:
- mastoidectomy and
- mastoidotomy.

Sinus applications would embody:
- septoplasty and
- procedures such as
  - the removal of septal spurs,
  - polypectomy,
  - antrostomy,
  - ethmoidectomy/sphenoethmoidectomy,
  - frontal sinus trephination and irrigation,
  - frontal sinus drill out,
  - endoscopic DCR and
  - trans-spehnoidal procedures.

Nasopharyngeal/Laryngeal procedures would comprise:
- adenoidectomy,
- tracheal,
- laryngeal polyectomy,
- laryngeal lesion debulking and
- tonsillectomy.

Head and neck procedures would encompass:
- soft tissue shaving,
- rhinoplasty (narrowing of the bony vault and revision of the bony pyramid),
- removal of fatty (adipose) tissue (lipo debridement) in the maxillary and mandibular regions of the face, and
- acoustic neuroma removal.

Additionally, an irrigation pump is integrated into the controller unit to provide irrigant in conjunction with the procedures.

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K992994

510(k) Number (if known): K992996

Device Name: Enable Endoscopic Bipolar Scissors

Indications For Use:

The Enable Endoscopic Bipolar Scissors is intended to cut tissue and control bleeding through coagulation during laparoscopic and general surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

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

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)