K012488

AUG 3 0 2001

Section 7- 510(k) Summary of Safety and Effectiveness

7.1 Statement	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92
7.2 Submitter	Endius, Inc. 23 West Bacon Street Plainville, MA. 02762
7.3 Company Contact	Susan Finneran Director Regulatory Affairs 508-643-0983
7.4 Device Name	**Proprietary Name:** Endius Bipolar Sheath **Common Name:** Bipolar Coagulation Device **Classification Name:** Electrosurgical cutting and coagulation device and accessories
7.5 Predicate Legally Marketed Devices	The Bipolar Sheath is substantially equivalent to the SLT Bipolar Sheath manufactured by Surgical Laser Technologies (Montgomery, PA)
7.6 Device Description	The Endius Bipolar Sheath is a stainless Steel tube covered with an insulation material that is intended to fit over an automated tissue removal blade. The device is intended to be connected to the Valley Lab's Force 2, FX, or EZ, generator by using the Bipolar Sheath Adapter that is intended to decrease the maximum voltage of the Valley Lab's Generator from 800 volts to 100 volts. This will ensure that the appropriate level of energy is transmitted to the Bipolar Sheath for the maximum performance.

K012488

7.7 Device Indications and Intended use

The Endius Bipolar Sheath is intended to be used in conjunction with the Endius XPS Microdebrider System to coagulate soft tissue during various spinal surgical procedures.

7.8 Substantial Equivalence

The Endius Bipolar Sheath is substantially equivalent to the SLT Bipolar Sheath manufactured by Surgical Laser Technologies (Montgomery, PA)

Table of Substantial Equivalence

Device Name	SLT Bipolar Sheath	Endius Bipolar Sheath and MDS Device
Intended use	**K981041:** The SLT Bipolar Sheath is intended to be used to coagulate soft tissue during ENT procedures. **K984018:** The SLT Bipolar Sheath is intended to be used to coagulate soft tissue during orthopedic procedures.	The Endius Bipolar Sheath is intended to be used coagulate soft tissue during various spinal surgical procedures.
Materials	Stainless Steel/ polyethylene	Stainless Steel, FEP coating, plastics, adhesives
Sterilization/ Labeling	Single Use, sterilized by 100% Ethylene Oxide	Single use, Sterilized by gamma irradiation
Sizes	3mm - 5mm	3.5-4.5mm
Exposed Tip Size	1.5 mm electrode	3.5-4.5mm
Length	8.1 cm	6-12 cm
Operating Mode	To be used with ESU Generator in Bipolar Mode	To be used with ESU Generator in Bipolar Mode

Applicant _____ Date 8/1/01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2001

Ms. Susan Finneran
Director Regulatory Affairs, Clinical Sciences
Endius, Inc.
23 West Bacon Street
Plainville, Massachusetts 02762

Re: K012488
Trade/Device Name: Endius Bipolar Sheath and Accessories
Regulation Number: 878.4400
Regulatory Class: II
Product Code: GEI
Dated: August 2, 2001
Received: August 3, 2001

Dear Ms. Finneran:

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 legally marketed predicate 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 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 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) 594-4659. 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Laikin, M.D. FOR

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012488

Device Name: Endius Bipolar Sheath and Accessories

Indications for Use: The Endius Bipolar Sheath is intended to be used to coagulate soft tissue during various spinal surgical procedures.

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

Concurence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012488