

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The SLT bipolar sheath is indicated for use with currently marketed debrider systems used in Ear Nose and Throat Surgery. The SLT bipolar sheath is intended to provide coagulation of tissue at the distal end of the debrider tip. This sheath is designed with a standard interface to allow use with most electrosurgical generators.

Description statements were not relied on to show substantial equivalence to legally marketed devices; instead, performance data from device validation is used. The comparison of intended use and technological features of this device to other legally marketed devices taken together with validation results indicate that this device is substantially equivalent to legally marketed predicate devices with regards to safety, effectiveness and intended use.

The intended use of this device is the same as the intended use of other bipolar electrocautery devices marketed to provide the same tissue effects. Therefore, all aspect of this device have predicates which are well accepted in the clinical community. This product simply provides an alternative to those currently marketed devices.



AUG 27 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Monica Ferrante
Regulatory Affairs
Surgical Laser Technologies
147 Keystone Drive
Montgomeryville, PA 18936-9638Re: K981041
SLT Bipolar Sheath
Dated: July 9, 1998
Received: July 13, 1998
Regulatory class: II
21 CFR 874.4250/Procode: 77 ERL
21 CFR 878.4400/Procode: 79 GEI

Dear Ms. Ferrante:

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 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) 594-4613. 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/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

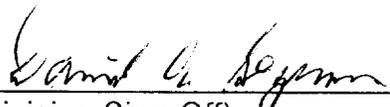
The SLT Bipolar Sheath is indicated for use with currently marketed debrider system tips used in Ear Nose and Throat Surgery. The SLT bipolar sheath is intended to provide coagulation of tissue at the distal end of the debrider tip. The sheath which incorporates the bipolar electrodes is designed with a standard interface to allow use with any electrosurgical system which meets the following requirements:

- Generator must operate in a Bipolar mode
- Generator must accept a standard banana plug connector

and will fit on any debrider tips which meet the following requirements:

- Debrider tip must be either 3.5mm or 4.0mm in diameter

This device is a prescription device.



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

510(k) Number K981041

Prescription Use 

(Per 21 CFR 801.109)