NOV 25 1998

K983050

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The SLT Pneumatic Cutter System is indicated for use in Ear Nose and Throat Surgery primarily sinus endoscopy, and orthopedic procedures primarily arthroscopy. The cutter is intended to achieve the removal of tissue, both soft tissue and bone with the appropriate handpiece. It will also provide suction and irrigation to the operative site.

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 debrider instruments 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 1998

Ms. Monica Ferrante
Regulatory Affairs
Surgical Laser Technologies, Inc.
147 Keystone Dr.
Montgomeryville, Pennsylvania 18936

Re: K983050
Trade Name: SLT Pneumatic Cutter System
Regulatory Class: II
Product Code: ERL
Dated: September 1, 1998
Received: September 1, 1998

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 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,

for 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

K983050

INDICATIONS FOR USE

The SLT Pneumatic Cutter System is intended to cut and remove soft tissue. The primary areas of use are Sinus Endoscopy (ENT) and Arthroscopy (Orthopedic) procedures. The tissue is cut with a disposable cutting blade which has an irrigation and suction port designed into its core. The tissue is automatically suctioned away once cut. The device can also drill bone material and automatically remove the bone dust and fragments through an internal suction port.

This device is a prescription device.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)

510(k) Number K983050