

k 980156

FEB 27 1998

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The SLT Select Fiber Delivery Systems and Contact Tips are intended to be used in general surgery as well as multiple surgical specialties such as Urology, Gynecology, ENT, Head and Neck, Gastroenterology, Neurosurgery, Thoracic surgery, Pulmonology, Plastic surgery and Orthopedics. The fiber delivery systems and tips achieve the precise tissue effects of incision, excision, vaporization and coagulation of tissue. The universal SMA-905 connector allows this family of fiber delivery systems to be used with any laser system of 532 to 1064 nm wavelength which accepts the SMA-905 connector.

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 laser fiber delivery systems and identical to the proprietary SLT Products currently 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 the ability to use the SLT fiber delivery systems with any 532 to 1064 nm wavelength laser system which accepts the SMA-905 connector.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 1998

Ms. Monica Ferrante
Regulatory Affairs
Surgical Laser Technologies
147 Keystone Drive
Montgomeryville, Pennsylvania 18936-9638

Re: K980156
Trade Name: SLT Select Fiber Delivery System
and Contact Tips
Regulatory Class: II
Product Code: GEX
Dated: January 1998
Received: January 16, 1998

Dear Ms. Ferrante:

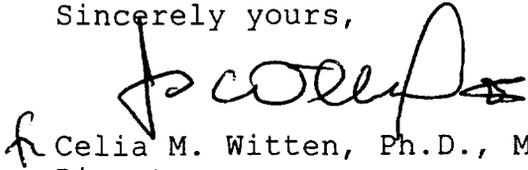
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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


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

K980156

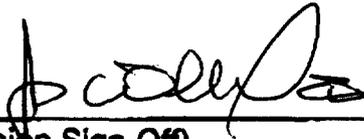
INDICATIONS FOR USE

The SLT Select Fiber Delivery Systems and Contact Tips are indicated for use in General Surgery as well as multiple surgical specialties such as Urology, Gynecology, ENT, Head and Neck, Gastroenterology, Neurosurgery, Thoracic surgery, Pulmonology, Plastic Surgery and Orthopedics. The fiber delivery systems achieve the precise tissue effects of incision, excision, vaporization and coagulation of tissue. The universal SMA-905 connector allows this family of fiber delivery systems and tips to be used with any laser system meeting the following requirements:

- Laser must operate at a wavelength between 532 and 1064 nanometers.
- Laser must operate in Continuous Wave (CW) or Quasi Continuous Wave (Quasi CW) mode.
- Laser must have a numerical apertures of 0.39 or less
- Laser must accept the universal SMA-905 connector.

Fiber Delivery Systems are cleared for use for the particular indications of the laser system to which they are attached.

This device is a prescription device.



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

510(k) Number K980156

Prescription Use X
(Per 21 CFR 801.109)