APR 21 1998

K972548

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The SLT CL MD Laser Systems are intended to be used in general surgery as well as multiple surgical specialties such as Urology, Gynecology, ENT, Head and Neck, Gastroenterology, Neurosurgery, Thorasic surgery, Pulmonology, Plastic surgery and Orthopedics. The fiber delivery systems achieve the precise tissue effects of incision, excision, vaporization and coagulation of tissue. This device is specifically intended for use in prostate procedures which treat the clinical condition of Benign Prostatic Hyperplasia. This device is currently cleared for market for multiple surgical indications.

Description statements were not relied on to show substantial equivalence to legally marketed devices; instead, performance data from device validation is used as well. 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. This information was provided in 510(k) K902241 which cleared the device for Genitourinary surgical procedures and K955813 which extended the Urology claims to include catheter removal within 24 hours. This submission will establish, based on clinical data, that the laser procedure for treatment of BPH is equivalent in safety and effectivness to the traditional electrosurgical procedure.

The safety of this device is shown by compliance to relevant safety standards for Laser systems devices such as UL 2601, IEC 601-1, IEC 601-2-22, etc. Product safety is also verified by Hazard analysis, software validation and performance testing to ensure the product performs as intended. The safety of the laser system was assessed and cleared for market under 510(k) K854669, K884815, K912793, and K930490.

The intended use of this device is the same as the intended use of many other products currently on the market. Specifically, there are SLT Products as well as competitors products which are intended to provide the identical tissue effects. Therefore, all aspect of this device have predicates which are well accepted in the clinical community. This product simply provides the clinical data to show that laser prostate procedures are substantially equivalent in safety and efficacy to the current Gold Standard Electrosurgical Procedure (TURP).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 1998

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

Re: K972548
Trade Name: SLT CL MD Contact Laser System and Delivery Fibers
Regulatory Class: II
Product Code: GEX
Dated: February 16, 1998
Received: February 17, 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

INDICATIONS FOR USE

The specific indication for use of the SLT® Contact Laser™ Fiber Delivery System is for the Incision, Excision, Coagulation and Vaporization of soft tissue for prostatectomy in treatment of Benign Prostatic Hyperplasia (BPH).

Vaporization of Prostatic Tissue - The Contact Laser Vaporization of the Prostate (CLVP) procedure vaporizes prostate lobe tissue as well as tissue obstructing the urinary channel. This procedure is indicated for prostates up to 45 grams in size.

Coagulation and Vaporization of Prostatic Tissue - The Coagulation and Hemostatic Resection of the Prostate (CHRP)™ coagulates the prostate lobe tissue and vaporizes tissue obstructing the urinary channel. This procedure is indicated for prostates up to 75 grams.

Prescription Use X
(Per 21 CFR 801.109)

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

510(k) Number K972548