V. Summary of Safety and Effectiveness

K960905

Summary of 21 CFR 807.87

JUN - 3 1996

A. Device Name:

1. Proprietary Name: SDL Diode Laser System and Associated Fiberoptic Delivery Systems

2. Common Name: Near-infrared Diode Laser System

B. Establishment Registration Number:

SLT-J, Ltd. has not yet registered as a medical device establishment with the FDA. The company intends to complete all regulatory filings prior to introducing the SDL diode laser system into interstate commerce.

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C. Device Classification:

Diode surgical laser systems are currently considered Class II medical devices subject to pre-market notification provisions for many surgical applications.

Although not formally classified, diode surgical laser delivery systems typically have been regulated as Class II devices.

Electrosurgery handpieces (pencils, electrodes) are considered Class II 79 GEI [21 CFR 878.4400]. SLT-J, Ltd. anticipates these accessory devices would receive the same classification if such energy delivery systems were officially classified.

D. Compliance With Standards

The SDL diode laser conforms with federal regulations and the performance standards 21 CFR 1040.10 and 1040.11 for medical laser systems. Certification reports will be submitted to CDRH certifying compliance with this standard and are currently in preparation and will be submitted by SLT-J, Ltd. prior to commercial distribution of this product.

E. Labeling

Product labels comply with 21 CFR 1040.10 and 1040.11 as applicable. An Operator's Manual for the SDL diode laser system is currently in preparation. A draft Operator's Manual is included in this submission (See Attachments).

Product labels comply with 21 CFR 801 as applicable for accessory devices. Copies of the proposed text for these package labels are located in Section IV of this submission.

F. Statement of Equivalence

In the opinion of SLT-J, Ltd., the SDL diode laser system, when used with any of the following fiberoptic delivery systems:

NEOS Alloy Scalpel (K#914197)
LCA, Inc. (Cincinnati, OH)

Fiber Cap (K#924120)
LCA, Inc. (Cincinnati, OH)

Hybrid Surgical Device (K#924160)
LCA, Inc. (Cincinnati, OH)

Closed End (K#931070)
LCA, Inc. (Cincinnati, OH)

Closed End/Electrocautery (K#932272)
LCA, Inc. (Cincinnati, OH)

Bipolar Dissector (K#901365)
LCA, Inc. (Cincinnati, OH)

is substantially equivalent to the use of any of the above-mentioned devices when used with any of the following medical devices which are used as a laser (energy) source:

Diomed® 25, 25W surgical diode laser system (K#s 914520, 914521), Diomedics Inc. (The Woodlands, TX)

ZOE Nd:YAG laser system (K#s 909128, 923991), LCA, Inc. (Cincinnati, OH)

Section III of this submission provides information in support of this equivalence claim.

This belief of equivalence is based upon the following facts:

1. The SDL diode laser system has the same operating characteristics as the diode laser system offered by Diomedics Inc with respect to power output, operating parameters and operating controls and indicators. The SDL diode laser system incorporates touch pad controls

for setting of operating parameters, uses identical input power (110 VAC) as the Diomed 25W diode laser system offered by Diomedics Inc. (The Woodlands, TX).

2. The SDL diode laser system uses the industry standard SMA 905 fiberoptic connector system for its fiberoptic delivery systems. This is identical to the connector system used by Diomedics (The Woodlands, TX). The delivery system which will be used with the SDL diode laser system will be able to directly attach to the fiberoptic connector system.

3. Due to the technologies used in the manufacturing of the NEOS family of fiberoptic delivery systems as well as the Bipolar Dissector, the laser system used with these products is not a dependent variable to achieve a desired tissue effect. The particular surface treatment used on the NEOS Alloy Scalpel, Fiber Cap, Hybrid Surgical Device and the Bipolar Dissector, provide a product which completely absorbs the laser energy, thus converting laser light energy into thermal energy, regardless of the wavelength of the laser light source.

   The Closed End and Closed End/Electrocautery fiberoptic delivery systems use swaged stainless steel hypo tubing to convert light energy transmitted through the fiberoptics into thermal energy, again regardless of the wavelength of the laser light source.

   Laboratory bench top studies were performed to compare temperature profiles of a NEOS Alloy Scalpel tip with respect to the use with a diode laser or a 1.06μ Nd:YAG laser system. Temperature plots were made at typical power settings of 3.5 and 6.5 watts. The maximum temperatures obtained using both laser devices were equivalent. These studies support the belief that the NEOS family of fiberoptic delivery systems and the

Bipolar Dissector can be used with a variety of sources of energy (i.e. - many different laser wavelengths) due to their surface coatings which makes these devices true heat sources independent of input laser wavelength.

In 1993, Judy et al reported a study in which comparisons of the depths of thermal coagulation in rabbit tissues obtained with a diode laser and a 1.06μ Nd:YAG laser using contact fibers. Results of this study support the equivalency of tissue thermal effects obtained with the diode and Nd:YAG lasers in a contact mode; and support the use of the diode laser as an alternative medical device.

4. The SDL diode laser system can be operated by either a footswitch or a fingerswitch. This technology is equivalent to, and has been offered since 1990 on Nd:YAG laser systems offered by Surgical Laser Technologies (The Oaks, PA) and LCA (Cincinnati, OH). This allows the operator to select between either footswitch or fingerswitch control of the fiberoptic delivery system.

Bibliography

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