

K 960086

JUN - 3 1996

V. SUMMARY OF SAFETY & EFFECTIVENESS

SUMMARY OF 21 CFR 807.87

A. Device Name:

1. Proprietary Name: DCL8 Enhanced Pulsed Nd:YAG Laser System and Associated Fiberoptic Delivery Systems
2. Common Name: Pulsed Nd:YAG Laser System

B. Establishment Registration Number:

SLT-J has not yet registered as a medical device establishment with FDA. The company intends to complete all regulatory filings prior to introducing the DCL8 Enhanced Pulsed Nd:YAG laser system into interstate commerce.

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C. Device Classification:

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

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

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

D. Compliance With Standards

The DCL8 Enhanced Pulsed Nd:YAG laser system 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 are currently in preparation and will be submitted by SLT-J prior to commercial distribution of this product.

The sponsor is unaware of any specific standards solely for fiberoptic laser delivery systems.

E. Labeling

Product labels comply with 21 CFR 1040.10 and 1040.11 as applicable. A Operator's Manual for the DCL8 Enhanced Pulsed Nd:YAG laser system is currently in preparation. A draft Operator's Manual is included in this submission (see Section II, Device Description).

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.

Promotional materials are not yet in preparation; therefore, they are not included with this submission.

F. Equivalence Statement

In the opinion of SLT-J, the Pulsed Nd:YAG laser system is substantially equivalent to the following systems:

SunLase Master Pulsed Nd:YAG laser system, Sunrise Technologies, Inc., (Fremont, CA)

SunLase Pulsed Nd:YAG laser system, Sunrise Technologies, Inc. (Fremont, CA)

PulseMaster 600 Pulsed Nd:YAG laser system, American Dental Technologies (Troy, MI)

PulseMaster 1000 Pulsed Nd:YAG laser system, American Dental Technologies (Troy, MI)

G. Summary of Safety and Effectiveness

The DCL8 Enhanced Pulsed Nd:YAG laser system is substantially equivalent to other pulsed Nd:YAG laser systems currently marketed by Sunrise Technologies (Fremont, CA) and American Dental Technologies (Troy, MI)

This belief is based upon the following facts:

1. The DCL8 Enhanced Pulsed Nd:YAG laser system is substantially equivalent to other pulsed Nd:YAG laser systems currently in interstate commerce for use in procedures for incision, excision, coagulation or vaporization of soft tissues, such as, but not limited to: subcutaneous tissues, striated and smooth muscle, mucous membranes, along with organs and glands, in both open, endoscopic and laparoscopic procedures. The delivery systems which can be used in conjunction with the DCL8 Enhanced Pulsed Nd:YAG laser system have previously been cleared for marketing by the FDA.

2. The DCL8 Enhanced Pulsed Nd:YAG laser system has the same operating characteristics as the pulsed Nd:YAG laser systems offered by Sunrise Technologies and American Dental Technologies with respect to average power to tissue, pulse rates, operating controls and indicators. The DCL8 Enhanced Pulsed Nd:YAG laser system incorporates a red diode aiming beam, touch pad controls for setting of operating parameters, and uses the same input power (110 VAC) as the pulsed Nd:YAG laser systems offered by Sunrise Technologies and American Dental Technologies.
3. The DCL8 Enhanced Pulsed Nd:YAG laser system uses the industry standard SMA 905 fiberoptic connector system for its fiberoptic delivery systems. This is identical to the connector systems used by Sunrise Technologies and American Dental Technologies. The delivery systems which will be used with the DCL8 Enhanced Pulsed Nd:YAG laser system have previously received market clearance for use with Nd:YAG laser systems to which the delivery systems can be attached.
4. The DCL8 Enhanced Pulsed Nd:YAG 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 delivery system.
5. Many of the delivery systems (NEOS Alloy Scalpels, Fiber Cap, Hybrid Surgical Device, Closed End, Closed End/Electrocautery and Bipolar Dissector) which are to be used with the DCL8 Enhanced Pulsed Nd:YAG laser system have already received market clearance for use with other Nd:YAG laser systems. Because of the configuration of these delivery systems, i.e., delivery of laser light to tissues, the source of laser energy is not important. The delivery systems still interact

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with tissue in a similar manner, regardless of the input (laser) source. The Super Scalpel behaves in a similar manner.

The Fiber Contact Handpiece is equivalent to those offered currently by Sunrise Technologies (Fremont, CA) and American Dental Technologies (Troy, MI) for their pulsed Nd:YAG laser systems. Additionally, Laserscope (San Jose, CA) offers an equivalent contact fiber handpiece assembly.