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F. 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: subcutaneous tissues, striated and smooth muscle, mucous membranes, along with organs and glands, in both open, endoscopic and microscopic 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.

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