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Trimedyne

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Summary of 510(k) Safety and Effectiveness Information

Trimedyne® Holmium:YAG Laser Systems and Fiber Optic Delivery Devices for Multispecialty Applications

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. Submitter Information: Trimedyne, Inc.
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II. Device Name

Proprietary: OmniPulse™ Holmium Laser (Model 1210)
OmniPulse-MAX™ Holmium Laser (Model 1210-VHP)
Not yet determined for Proposed Holmium Laser
Not yet determined for Proposed Delivery Systems

Common: Holmium:Yttrium Aluminum Garnet (Ho:YAG) laser system
Laser Fiber

Classification: Laser-powered instrument
Accessory to Laser-powered instrument

III. Predicate Device

The predicate devices for the laser systems are the Tissue Technologies, Inc. TRU-PULSE™ Pulsed CO_2 Surgical Laser System, Coherent® UltraPulse® 5000C Aesthetic Laser System, and the Trimedyne Optilase® 1000-100 Nd:YAG Laser.

The predicate devices for the fiber optic delivery systems are the Omni™ Switchtip System and the Tapertip™ Multiuse Holmium Arthroscopy Handpieces, both of which are currently marketed by Trimedyne.

IV. Device Description

The OmniPulse and OmniPulse-MAX Holmium Lasers are medical grade, Class IV, pulsed, solid-state, Ho:YAG laser systems designed to deliver pulsed infrared laser energy with a wavelength of 2.1 micron and 350 microsecond pulse width. Menu-driven control options allow the user to select pulse repetition rate, output energy, and maximum lasing period.

The Proposed Laser System is a medical grade, Class IV, pulsed, solid-state Ho:YAG laser system designed to deliver pulsed infrared laser energy with a wavelength of 2.1 micron. The pulsewidth may either be 350 microseconds or variable up to a maximum of 350 microseconds, depending on the configuration of the laser. Menu-driven control options allow the user to select pulse repetition rate, output energy, pulsewidth (if variable), and lasing duration.

The proposed delivery systems are single use, contact or near-contact fiber optic energy delivery devices consisting of a flexible bundle of buffered optical fibers contained in a stainless steel shaft; the proximal end of the laser fiber optic incorporates either a custom or and SMA connector. These devices are shipping sterile/non-pyrogenic; from time-to-time they may be offered in non-sterile form in which case the user will be provided with sterilization instructions.

V. Intended Use

The laser systems are intended for use in multispecialty applications, including dermatology and plastic surgery, discectomy, general surgery, genitourinary surgery, lithotripsy, orthopedic surgery, endoscopic sinus surgery, and otorhinolaryngology.

The fiber optic delivery systems are intended for use with any holmium laser (with a compatible connector) for its cleared applications.

VI. Technological Characteristics

The Trimedyne laser systems included in this submission are Holmium:YAG lasers which emit light at a wavelength of 2.1 microns (near infrared) and a maximum pulse width of 350 microseconds.

The OmniPulse has the capability of attaining a maximum output of 40 watts of power (maximum 40 watts/3500 mJ and maximum frequency mode of 25 pps).

The OmniPulse-MAX has the capability of attaining a maximum output 80 watts of power (maximum 80 watts/3500 mJ and maximum frequency mode of 60 pps). This laser can operate in either single- or double-pulse mode and has an integrated power meter to enable the user to easily measure the output power.

The Proposed Laser System has the capability of attaining a maximum output of 100 watts of power (maximum 100 watts/4200 mJ and maximum frequency mode of 100 pps).

The proposed delivery devices differ from their predicate devices in that they are designed with multiple fibers, as opposed to a single-fiber configuration.

VII. Nonclinical Tests

The proposed delivery systems were subjected to a series of tests; these tests included sterilization, efficiency, performance and mechanical studies. Biocompatibility data exhibiting the acceptability of materials used in the fiber optic delivery systems was also submitted.

VIII. Clinical Tests

No clinical tests were submitted in this 510(k).

IX. Conclusions Drawn from Testing

The proposed delivery systems are biocompatible and exhibit acceptable performance and mechanical properties when used according to their labeling.