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Trimedyne

K970422

Summary of 510(k) Safety and Effectiveness Information

Trimedyne® Right Angle Laser Fibers and Optilase® Lasers for the Treatment of BPH at 60 watts of Laser Power

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:**

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II. **Device Name**

Proprietary:
- Optilase® Model 1000 Nd:YAG Laser System
- Optilase® Model 4000 Nd:YAG Laser System
- Optilase® PL100 Model 1000-100 Nd:YAG Laser System
- UroGold™ Right Angle Laser Fibers
- UroMax™ Right Angle Laser Fibers

Additional proprietary names may be used for other Right Angle Laser Fiber configurations.

Common:
- Laser-powered Instrument
- Laser Fiber

Classification:
- Nd:YAG Laser System
- Accessory to Laser-powered Instrument - Not Classified

III. **Predicate Device**

The predicate devices are those cleared under 510(k) K954597.

IV. **Device Description**

The Optilase laser systems are continuous wave Nd:YAG energy sources equipped with an aiming beam, adjustable power output, and a fiber optic connector.

The Right Angle Laser Fibers are fiber optic Nd:YAG energy delivery systems consisting of : a three meter length of buffered quartz fiber, a tip which allows delivery of laser energy, and a fiber optic connector.

V. Intended Use

The Right Angle Laser Fibers and Optilase Lasers are indicated for a wide variety of surgical uses including incision, excision, resection, vaporization, ablation, coagulation and hemostasis. In addition, they are indicated for coagulation of soft tissue for prostatectomy in the treatment of benign prostatic hyperplasia (BPH).

VI. Technological Characteristics

There are no technological differences between these devices and those cleared under K954597.

VII. Nonclinical Tests

No nonclinical tests were submitted in this Premarket Notification.

VIII. Clinical Tests

A limited clinical study was undertaken to provide information related to Visual Laser Ablation of the Prostate (VLAP) with 60 watts of laser power. These data were compared to data obtained from an earlier study in which VLAP at 40 watts of laser power was compared to TURP.

IX. Conclusions Drawn from Testing

The results of the comparative data submitted in this Premarket Notification demonstrate that VLAP, whether it be performed at 40 watt or 60 watt treatment parameters, is a viable alternative to TURP.