

K954597



MAR 11 1996

Summary of 510(k) Safety and Effectiveness Information
Trimedyn® Right Angle Laser Fibers and
Optilase® Nd:YAG Laser System Models 1000, 4000, and 1000-100 (PL100)

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: Trimedyn, Inc.
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Summary Date: October 2, 1995

II. Device Name

Right Angle Laser Fibers:

Proprietary: Not yet selected

Common: Laser fiber

Classification: Accessory to Laser-powered Instrument (unclassified)

Optilase Lasers:

- Proprietary:**
- Optilase® Model 1000 Nd:YAG Laser System
 - Optilase® Model 4000 Nd:YAG Laser System
 - Optilase® PL100 Model 1000-100 Nd:YAG Laser System

Common: Neodymium Yttrium Aluminum Garnet (Nd:YAG) laser system

Classification: Laser-powered Instrument

III. Predicate Device

The predicate devices for the intended use are various configurations of the Trimedyn Right Angle Laser Fiber cleared under 510(k) number K944204 and the Trimedyn Optilase Nd:YAG Laser Systems cleared under 510(k) numbers K922497 and K932883.

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IV. Device Description

The Right Angle Laser Fiber is a fiber optic Nd:YAG energy delivery system consisting of: a 3 meter length of buffered quartz fiber, a tip which allows delivery of laser energy, and a fiber optic connector.

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

V. Intended Use

The Right Angle Laser Fiber and Optilase Lasers are indicated for a wide variety of surgical uses including incision, excision, resection, vaporization, ablation, coagulation, and hemostasis for the treatment of benign prostatic hyperplasia (BPH) and other urological conditions.

Viewing scopes, which can be either flexible or rigid, may be used for visualization during laser procedures.

VI. Technological Characteristics

There are no technological characteristics differences between the devices cleared under this 510(k) and the predicate devices with regard to the intended use.

VII. Nonclinical Tests

No nonclinical tests were submitted in this Premarket Notification.

VIII. Clinical Tests

A prospective, controlled and well-matched study was undertaken to compare visual laser ablation of the prostate (VLAP) to transurethral resection of the prostate (TURP).

IX. Conclusions Drawn from Testing

The clinical data show that the Trimeddyne Right Angle Laser Fibers and Optilase Nd:YAG Laser Systems are safe and effective for treatment of Benign Prostatic Hyperplasia (BPH).