



K 964585

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Summary of 510(k) Safety and Effectiveness Information

Trimedyne® Multiuse Switchable Tips

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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- Contact Person:** Susan H. Gamble
Director, Regulatory Affairs & Quality Assurance
- Summary Date:** November 14, 1996
- II. **Device Name**
- Proprietary:** Resposable OmniTip™ Switchable Tips
- Common:** Laser Fibers
- Classification:** Accessories to Laser-Powered Instrument (unclassified)
- III. **Predicate Device**
- The predicate devices are the Trimedyne Omni™ Switchtip System and Tapertip™ Endfiring Multiuse Handpieces.
- IV. **Device Description**
- The Multiuse Switchable Tip is a fiber optic energy delivery device consisting of a near-contact fixed laser fiber contained in a stainless steel shaft; it attaches to the Omni™ Multiuse Handpiece through a quick-connect mechanism.
- V. **Intended Use**
- These devices are intended for use with any holmium laser (with a compatible connector) for its cleared applications.
- VI. **Technological Characteristics**
- The devices differ from their predicate devices due only to the incorporation of minor materials and configuration changes which allow for steam sterilization/reuse.
- VII. **Nonclinical Tests**
- The devices were subjected to a series of tests; these tests included sterilization, mechanical, biological, and performance studies.

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VIII. Clinical Tests

No clinical tests were submitted in this Premarket Notification.

IX. Conclusions Drawn from Testing

The devices are biocompatible, perform as intended, and have acceptable mechanical properties when used according to their labeling.