

**K922497 OPTILASE ND:YAG MODELS 1000/4000 SURG LASER SYSTEM**Mar 1, 1994  
643 days to decisionK922497 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k922497/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 27, 1992
Decision date	Mar 1, 1994
Days to decision	643 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Trimedyne, Inc.</b>
Location	Walker, MI, US
Contact	PAUL S KRAMSKY
Website	<a href="http://www.trimedyne.com/">http://www.trimedyne.com/</a>
510(k) history	58 submissions · 58 cleared · 1981-2005

Trimedyne, Inc. is a manufacturer of Holmium:YAG lasers and surgical peripherals. The company specializes in laser-based surgical solutions for minimally invasive procedures across multiple specialties including urology, orthopedics, spine surgery, and general surgery. Trimedyne has received FDA 510(k) clearances from total submissions since its first clearance in 1981. The company's regulatory focus centers on General & Plastic Surgery devices, which represent 83% of its submission history. The latest clearance on record dates to 2005, reflecting the company's historical...