

**K932883 OPTILASE MODEL 1000-100 ND: YAG LASER SYSTEM**Jun 21, 1994  
372 days to decisionK932883 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k932883/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 14, 1993
Decision date	Jun 21, 1994
Days to decision	372 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Trimedyn, Inc.</b>
Location	Walker, MI, US
Contact	VICTOR HAM
Website	<a href="http://www.trimedyn.com/">http://www.trimedyn.com/</a>
510(k) history	58 submissions · 58 cleared · 1981-2005

Trimedyn, 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. Trimedyn 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...

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