

**K970422 RIGHT ANGLE LASER FIBERS**Apr 21, 1997  
77 days to decisionK970422 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k970422/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 3, 1997
Decision date	Apr 21, 1997
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary
Other names	OPTILASE ND:YAG LASER;OPTILASE PL100 ND LASER SYSTEMS

**APPLICANT**

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Company	<b>Trimedyn, Inc.</b>
Location	Walker, MI, US
Contact	SUSAM H GAMBLE
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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