

**K870505 OPTILASE YAG MODEL 1000 SURG LASER  
SYS/PULMON APPL**Aug 7, 1987  
184 days to decisionK870505 · Product code: **LLO** · Anesthesiology  
Source: <https://www.510kdatabase.net/k870505/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Neodymium:yag, Pulmonary Surgery (LLO)
Date received	Feb 4, 1987
Decision date	Aug 7, 1987
Days to decision	184 days
Third-party review	No

**APPLICANT**

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Company	<b>Trimedyne, Inc.</b>
Location	Walker, MI, US
Contact	KIMBERLEY DONEY
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...

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