

**K925124 TRIMEDYNE MODEL 1210 OMNIPULSE HOLMIUM  
LASE SYST**Mar 1, 1994  
504 days to decisionK925124 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k925124/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 13, 1992
Decision date	Mar 1, 1994
Days to decision	504 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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...