

K934865 OMNIPULSE MODEL 1210-VHP HO:YAG LASER SYSTEMMay 12, 1994
212 days to decisionK934865 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k934865/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 12, 1993
Decision date	May 12, 1994
Days to decision	212 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Trimedyn, Inc.
Location	Walker, MI, US
Contact	LOUIE GORYOKA
Website	http://www.trimedyn.com/
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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