

K951562 OMNIPULSE-MAX HOLMIUM LASERJul 21, 1995
108 days to decisionK951562 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k951562/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 4, 1995
Decision date	Jul 21, 1995
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Trimedyn, Inc.
Location	Walker, MI, US
Contact	SUSAN H GAMBLE
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...
