

K962632 OMNIPULSE/OMNIPULSE-MAXJan 16, 1997
195 days to decisionK962632 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k962632/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 5, 1996
Decision date	Jan 16, 1997
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Trimedyne, Inc.
Location	Walker, MI, US
Contact	SUSAN H GAMBLE
Website	http://www.trimedyne.com/
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...
