

K053457 VAPORMAX IIDec 21, 2005
8 days to decisionK053457 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k053457/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 13, 2005
Decision date	Dec 21, 2005
Days to decision	8 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Trimedyne, Inc.
Location	Walker, MI, US
Contact	GLENN D YEIK
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...
