

K895874 OPTILASE YAG MODEL 1000Jan 3, 1990
91 days to decisionK895874 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k895874/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 4, 1989
Decision date	Jan 3, 1990
Days to decision	91 days
Third-party review	No

APPLICANT

Company	Trimedyne, Inc.
Location	Walker, MI, US
Contact	MERRITT M GIRGIS
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...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k895874/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026