FDA 510(k) Premarket Notification

K890279 MODIFIED MODEL 1000 OPTILASE(TM) ND:YAG LASER

CLEARED

Feb 7, 1989
26 days to decision

K890279 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k890279/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 12, 1989
Decision date	Feb 7, 1989
Days to decision	26 days
Third-party review	No

APPLICANT

Company	**Trimedyne, Inc.**
Location	Walker, MI, US
Contact	KIMBERLEY DONEY
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...