K992574 OMNIPULSE HOLMIUM LASER SYSTEM MODEL 1210, OMNIPULSE-MAX HOLMIUM LASER SYSTEM MODELS 1210-VHP, 1500A

CLEARED

Oct 29, 1999
88 days to decision

K992574 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k992574/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 2, 1999
Decision date	Oct 29, 1999
Days to decision	88 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...