

K920934 HALOCATH LASER CATHETERSApr 29, 1992
61 days to decisionK920934 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k920934/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 28, 1992
Decision date	Apr 29, 1992
Days to decision	61 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Trimedynne, Inc.
Location	Walker, MI, US
Contact	PAUL S KRAMSKY
Website	http://www.trimedynne.com/
510(k) history	58 submissions · 58 cleared · 1981-2005

Trimedynne, 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. Trimedynne 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...
