

K903154 CONTACT FIBERS,SURGICAL PROBES & NON-CONTACT FIBERNov 23, 1990
128 days to decisionK903154 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k903154/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 18, 1990
Decision date	Nov 23, 1990
Days to decision	128 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...
