FDA 510(k) Premarket Notification

K964585 RESPOSABLE OMNI TIP(TM) SWITCHABLE TIPS (MULTIPLE)

CLEARED

Apr 17, 1997
153 days to decision

K964585 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k964585/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 15, 1996
Decision date	Apr 17, 1997
Days to decision	153 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...