FDA 510(k) Premarket Notification

# K895774 GYN-PROBE

**CLEARED**

Jan 3, 1990
99 days to decision

K895774 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k895774/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Sep 26, 1989 |
| Decision date | Jan 3, 1990 |
| Days to decision | 99 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...