

K843628 HOTIP HEMOSTATIC PROBENov 12, 1985
424 days to decisionK843628 · Product code: **LNK** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k843628/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Laser For Gastro-urology Use (LNK) |
| Date received | Sep 14, 1984 |
| Decision date | Nov 12, 1985 |
| Days to decision | 424 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Trimedyne, Inc. |
| Location | Walker, MI, US |
| 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...

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