FDA 510(k) Premarket Notification

K840722 ENTEROSCOPE

CLEARED

Jun 7, 1984
111 days to decision

K840722 · Product code: **FDA** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k840722/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enteroscope And Accessories (FDA)
Date received	Feb 17, 1984
Decision date	Jun 7, 1984
Days to decision	111 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...