FDA 510(k) Premarket Notification

K841318 A.S.A.P.

CLEARED

Jul 18, 1984
107 days to decision

K841318 · Product code: **LDR** · General Hospital
Source: https://www.510kdatabase.net/k841318/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Infusion, Intravascular, Electronic (LDR)
Date received	Apr 2, 1984
Decision date	Jul 18, 1984
Days to decision	107 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...