

K810605 CHEMATIC BICARBONATE DIALYSATE SYSTEMJun 16, 1981
102 days to decisionK810605 · Product code: **FKR** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k810605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Subsystem, Proportioning (FKR)
Date received	Mar 6, 1981
Decision date	Jun 16, 1981
Days to decision	102 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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