FDA 510(k) Premarket Notification

K801966 HEMO-CATH II KIDNEY DIALYSIS CATHETER

CLEARED

Sep 26, 1980
38 days to decision

K801966 · Product code: **FIE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k801966/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Aug 19, 1980
Decision date	Sep 26, 1980
Days to decision	38 days
Third-party review	No

APPLICANT

Company	**Medical Components, Inc.**
Location	Mchenry, IL, US
510(k) history	63 submissions · 55 cleared · 1980-2025