

K023162 FRESENIUS PUNCTUR-GUARD FISTULA NEEDLE SETSMar 20, 2003
178 days to decisionK023162 · Product code: **FIE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k023162/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Sep 23, 2002
Decision date	Mar 20, 2003
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fresenius Medical Care
Location	Lexington, MA, US
Contact	NICHOLE RIEK
Website	http://www.fmc-ag.com/
510(k) history	7 submissions · 7 cleared · 2000-2024

Fresenius Medical Care is a global provider of dialysis products and services. The company operates with a manufacturing facility in Lexington, US. It specializes in Gastroenterology & Urology devices for kidney replacement therapy and renal care. The company has received FDA 510(k) clearances from total submissions. All submissions focus on Gastroenterology & Urology devices. Fresenius Medical Care's regulatory activity spans from 2000 to 2024, with its most recent clearance in 2024, demonstrating continued innovation in renal care technologies. The company's cleared dev...