FDA 510(k) Premarket Notification

K190459 Hemoflow F3 and F4 Dialyzers

CLEARED

Aug 23, 2019
178 days to decision

K190459 · Product code: **FJI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k190459/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	Feb 26, 2019
Decision date	Aug 23, 2019
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fresenius Medical Care Renal Therapies Group, LLC**
Location	Waltham, MA, US
Contact	Denise Oppermann
Website	https://www.freseniusmedicalcare.com
510(k) history	51 submissions · 51 cleared · 2013-2026

Fresenius Medical Care Renal Therapies Group, LLC is a medical device manufacturer based in Waltham, US. The company specializes in renal therapy and dialysis technologies. The company has received FDA 510(k) clearances from total submissions since 2013. 96% of submissions focus on Gastroenterology & Urology devices, reflecting the company's core expertise in dialysis and renal replacement therapies. The latest clearance was in 2026, confirming active regulatory engagement. Recent cleared devices include hemodialysis systems, dialyzers, body composition monitors, and dial...