FDA 510(k) Premarket Notification

K250836 14F Duo-Flow® Side X Side Double Lumen Catheter

CLEARED

Aug 12, 2025
145 days to decision

K250836 · Product code: **MPB** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k250836/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Non-implanted (MPB)
Date received	Mar 20, 2025
Decision date	Aug 12, 2025
Days to decision	145 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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