FDA 510(k) Premarket Notification

CLEARED

K243607 Moda-flx Hemodialysis System™ Cartridge (102121-001)

Dec 20, 2024
29 days to decision

K243607 · Product code: **FJK** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k243607/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Set, Tubing, Blood, With And Without Anti-regurgitation Valve (FJK)
Date received	Nov 21, 2024
Decision date	Dec 20, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Diality, Inc.**
Location	Irvine, CA, US
Contact	Clayton Poppe
510(k) history	2 submissions · 2 cleared · 2024-2024