

K233798 Moda-flx Hemodialysis System and CartridgeAug 2, 2024
247 days to decisionK233798 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k233798/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Nov 29, 2023
Decision date	Aug 2, 2024
Days to decision	247 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

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