FDA 510(k) Premarket Notification

K233557 HemoCare Hemodialysis System

CLEARED

Jul 12, 2024
249 days to decision

K233557 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k233557/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Nov 6, 2023
Decision date	Jul 12, 2024
Days to decision	249 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Deka Research and Development**
Location	Manchester, NH, US
Contact	Paul Smolenski
510(k) history	11 submissions · 11 cleared · 2015-2025