FDA 510(k) Premarket Notification

K242155 DBB-06 PRO Hemodialysis Delivery System (DBB-06 PRO)

CLEARED

May 15, 2025
296 days to decision

K242155 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k242155/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jul 23, 2024
Decision date	May 15, 2025
Days to decision	296 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**NIKKISO CO., LTD.**
Location	Mchenry, IL, US
Contact	Satoko Hina
510(k) history	11 submissions · 11 cleared · 1981-2025

REGULATORY CONSULTANT

Consulting firm	**Healthcare Innovation Catalysts, Inc.**
Contact	Brittany Valdez Nava

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov