

K152938 DBB-06 Hemodialysis Delivery SystemMar 18, 2016
165 days to decisionK152938 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k152938/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Oct 5, 2015
Decision date	Mar 18, 2016
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152938/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026