FDA 510(k) Premarket Notification

K152938 DBB-06 Hemodialysis Delivery System

CLEARED

Mar 18, 2016
165 days to decision

K152938 · 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