

K091978 DBB-06 HEMODIALYSIS DELIVERY SYSTEMMar 25, 2010
267 days to decisionK091978 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k091978/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jul 1, 2009
Decision date	Mar 25, 2010
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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