K061519 MODIFICATION TO DBB-05 HEMODIALYSIS DELIVERY SYSTEM

CLEARED

Sep 28, 2007
484 days to decision

K061519 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k061519/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jun 1, 2006
Decision date	Sep 28, 2007
Days to decision	484 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