FDA 510(k) Premarket Notification

K994198 HEMOFEEL-CH, MODELS CH-0.35L, CH-0.6L, CH-1.0L

CLEARED

Aug 25, 2000
256 days to decision

K994198 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k994198/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Dec 13, 1999
Decision date	Aug 25, 2000
Days to decision	256 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Toray Industries (America), Inc.**
Location	New York, NY, US
Contact	LISA S JONES
510(k) history	18 submissions · 18 cleared · 1986-2004