

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

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k994198/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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