

K973516 CAPIOX HEMOCONCENTRATORJan 30, 1998
135 days to decisionK973516 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k973516/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Sep 17, 1997
Decision date	Jan 30, 1998
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Medical Corp.
Location	Elkton, MD, US
Contact	SANDI HARTKA
510(k) history	143 submissions · 143 cleared · 1980-2011

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