FDA 510(k) Premarket Notification

K000028 RENAFLO II HF 2000 HEMOFILTER

CLEARED

Apr 4, 2000
90 days to decision

K000028 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k000028/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jan 5, 2000
Decision date	Apr 4, 2000
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Minntech Corp.**
Location	Minneapolis, MN, US
Contact	RICHARD M ORMSBEE
510(k) history	33 submissions · 33 cleared · 1987-2012