FDA 510(k) Premarket Notification

K830487 HEMO-PROCESSING SYSTEM

CLEARED

Apr 28, 1983
72 days to decision

K830487 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k830487/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Feb 15, 1983
Decision date	Apr 28, 1983
Days to decision	72 days
Third-party review	No

APPLICANT

Company	**Sartorius Filters, Inc.**
Location	Mchenry, IL, US
510(k) history	8 submissions · 8 cleared · 1982-1985