FDA 510(k) Premarket Notification

K001283 LIFEMATE HEMOFILTRATION SYSTEM

CLEARED

Jan 17, 2001
271 days to decision

K001283 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k001283/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Apr 21, 2000
Decision date	Jan 17, 2001
Days to decision	271 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nxstage Medical, Inc.**
Location	Tewksburt, MA, US
Contact	JEFFREY BURBANK
510(k) history	51 submissions · 51 cleared · 2001-2024