K012510 MODIFICATION TO: LIFEMATE HEMOFILTRATION SYSTEM

CLEARED

Oct 19, 2001
74 days to decision

K012510 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k012510/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Aug 6, 2001
Decision date	Oct 19, 2001
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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