FDA 510(k) Premarket Notification

K003425 CLIRANS E-SERIES HOLLOW FIBER DIALYZERS

CLEARED

Feb 1, 2001
90 days to decision

K003425 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k003425/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Nov 3, 2000
Decision date	Feb 1, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Terumo Medical Corp.**
Location	Elkton, MD, US
Contact	YUK-TING LEWIS
510(k) history	143 submissions · 143 cleared · 1980-2011