

K003425 CLIRANS E-SERIES HOLLOW FIBER DIALYZERSFeb 1, 2001
90 days to decisionK003425 · Product code: **KDI** · Gastroenterology & UrologySource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003425/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026