FDA 510(k) Premarket Notification

K122343 PUREFLUX-H HEMODIALYZER

CLEARED

May 7, 2013
277 days to decision

K122343 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k122343/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Aug 3, 2012
Decision date	May 7, 2013
Days to decision	277 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nipro Medical Corporation**
Location	Lexington, KY, US
Contact	CAROLYN GEORGE
510(k) history	34 submissions · 34 cleared · 2005-2026