

K122343 PUREFLUX-H HEMODIALYZERMay 7, 2013
277 days to decisionK122343 · 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

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