

K140191 ELISIO-H HEMODIALYZERApr 14, 2014
77 days to decisionK140191 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k140191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jan 27, 2014
Decision date	Apr 14, 2014
Days to decision	77 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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