

K131381 ELISIO-H HEMODIALYZERDec 19, 2013
219 days to decisionK131381 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k131381/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	May 14, 2013
Decision date	Dec 19, 2013
Days to decision	219 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131381/> 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 June 7, 2026