

**K131935 ELISIO-H HEMODIALYZER, ELISIO-M HEMODIALYZER**Dec 20, 2013  
176 days to decisionK131935 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k131935/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jun 27, 2013
Decision date	Dec 20, 2013
Days to decision	176 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131935/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 7, 2026