

K260533 ELISIO™-HMar 19, 2026
30 days to decisionK260533 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k260533/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Feb 17, 2026
Decision date	Mar 19, 2026
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nipro Medical Corporation
Location	Lexington, KY, US
Contact	Jessica Oswald-Mcleod
510(k) history	34 submissions · 34 cleared · 2005-2026

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