K261399 ELISIO™-HX

CLEARED

Jul 28, 2026
90 days to decision

K261399 · Product code: **QAX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k261399/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemodialyzer With Expanded Solute Removal Profile (QAX)
Date received	Apr 29, 2026
Decision date	Jul 28, 2026
Days to decision	90 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	35 submissions · 35 cleared · 2005-2026

CLINICAL EVIDENCE - NCT07058909

Premarket Clinical Safety Assessment of the ELISIO™-HX

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	22 patients (actual)
Study sites	1 site
Condition studied	Renal Failure; Acute Renal Failure; Chronic Renal Failure; Chronic Kidney Diseases; End Stage Renal Disease
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Feb 25, 2026
Sponsor	Nipro Medical Corporation (Industry)

Primary outcome

Change in serum level of albumin

Secondary outcome

Change in Factor VII

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT07058909