July 28, 2026

Nipro Medical Corporation
Jessica Oswald-Mcleod
Director, Regulatory Affairs
3150 NW 107th Ave.
Miami, Florida 33172

Re: K261399
Trade/Device Name: Elisio™-HX
Regulation Number: 21 CFR 876.5862
Regulation Name: Hemodialyzer With Expanded Solute Removal Profile
Regulatory Class: Class II
Product Code: QAX
Dated: April 29, 2026
Received: April 29, 2026

Dear Jessica Oswald-Mcleod:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

MAURA ROONEY -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K261399 |

Please provide the device trade name(s).

ELISIO™-HX

Please provide your Indications for Use below.

The ELISIO™-HX dialyzer is indicated for patients with chronic kidney failure who are prescribed intermittent hemodialysis. It provides an expanded solute removal profile with increased removal of various middle molecules (up to 45 KDa) that may play a pathologic role in the uremic clinical syndrome. This dialyzer is not intended for hemofiltration or hemodiafiltration therapy. The total extracorporeal blood volume for this dialyzer and the set should represent less than 10% of the patient's blood volume.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

# 510(k) Summary: ELISIO™-HX

Date Prepared: April 28, 2026

**Contact Details (21 CFR 807.92(a)(1))**

| | |
|---|---|
| Applicant Name | Nipro Medical Corporation |
| Applicant Address | 3150 NW 107th Ave. Miami FL 33172 United States |
| Applicant Contact Telephone | 305-432-6699 |
| Applicant Contact | Mrs. Jessica Oswald-McLeod, Director, Regulatory Affairs |
| Applicant Contact Email | Jessicao@nipromed.com |

**Device Name (21 CFR 807.92(a)(2))**

| | |
|---|---|
| Device Trade Name | ELISIO™-HX |
| Common Name | Hemodialyzer |
| Classification Name | Hemodialyzer with expanded solute removal profile |
| Regulation Number | 876.5862 |
| Product Code | QAX |

**Legally marketed predicate device (21 CFR 807.92(a)(3))**

| | | |
|---|---|---|
| Predicate # DEN190042 | Predicate Trade Name: Theranova | Product Code: QAX |
| Predicate # K260533 | Predicate Trade Name: ELISIO™-H | Product Code: KDI |

**Device Description Summary (21 CFR 807.92(a)(4))**

The ELISIO™-HX hemodialyzer is an extracorporeal medical device designed to perform the function of an artificial kidney in patients with end-stage renal disease (ESRD). It is comprised of two fluid pathways, blood and dialysate, separated by a semi-permeable membrane composed of Polyethersulfone (PES). During hemodialysis, the patient's blood circulates through the blood compartment of the dialyzer, while dialysate flows in a countercurrent direction through the adjacent dialysate compartment. The semipermeable membrane facilitates selective diffusion of uremic toxins, electrolytes, and excess fluid from the blood into the dialysate, driven by concentration gradients and transmembrane pressure. The purified blood is then returned to the patient, while the spent dialysate containing the removed solutes is discarded.

The ELISIO™-HX connects to the patient through an ISO 8637-2 compliant blood tubing set and is intended for use exclusively with dialysis machines equipped with an ultrafiltration controller or accurate fluid-balancing system. The POLYNEPHRON™ (Polyethersulfone) membrane incorporates an enlarged pore structure and optimized membrane geometry to enhance the clearance of middle-molecule uremic toxins (up to 45 kDa) while maintaining minimal albumin loss. The polypropylene housing is not made with BPA or DEHP.

The ELISIO™-HX is available in four sizes distinguished by membrane surface area: 1.5, 1.7, 1.9, and 2.1 m². It is sterile (gamma radiation) and non-pyrogenic with a three-year shelf life. No integrated components or accessories are included.

**Intended Use/Indications for Use (21 CFR 807.92(a)(5))**
The ELISIO™-HX dialyzer is indicated for patients with chronic kidney failure who are prescribed intermittent hemodialysis. It provides an expanded solute removal profile with increased removal of various middle molecules (up to 45 KDa) that may play a pathologic role in the uremic clinical syndrome. This dialyzer is not intended for hemofiltration or hemodiafiltration therapy. The total extracorporeal blood volume for this dialyzer and the set should represent less than 10% of the patient's blood volume.

**Indications for Use Comparison (21 CFR 807.92(a)(5))**
The subject device Indications for Use are identical to the predicate, Theranova (DEN190042)

**Technological Comparison (21 CFR 807.92(a)(6))**
The ELISIO™-HX and Theranova dialyzers share the same technological characteristics of intended use, indications for use, operating principles, and key design features. Both devices are sterile, single-use, medium cutoff (MCO) hemodialyzers intended for the extracorporeal treatment of patients with renal failure and are designed with an expanded solute removal profile that targets middle molecules. They function through the same mechanism of diffusion across a semi-permeable hollow-fiber membrane. Each is intended for use by qualified clinicians within an in-patient clinical setting and must be used with dialysis machines equipped with ultrafiltration control.

The subject device is identical in materials, manufacturing processes, sterilization method, shelf life, and packaging to the reference device ELISIO™-H (K260533).

**Non-Clinical and/or Clinical Tests Summary & Conclusions (21 CFR 807.92(b))**
Performance testing was conducted according to ISO 8637-1: 2017 - Extracorporeal systems for blood purification - Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators and the FDA Guidance for the Content of Premarket Notifications for Conventional and High Permeability Hemodialyzers. Testing included Mechanical Characteristics (Structural integrity: positive and negative pressure, Blood compartment integrity, Connectors verification) and Performance Characteristics (Solute clearance: Urea, Creatinine, Phosphate, Vitamin B12, Inulin, Myoglobin, Potassium (K), TNF-α and IL-6 and Cytochrome C; Sieving coefficients: Urea, Creatinine, Inulin, Vitamin B12, β2-Microglobulin, Myoglobin and Albumin; Ultrafiltration rate; Ultrafiltration coefficient; Blood compartment volume; Pressure drop; Endotoxin testing (ANSI/AAMI ST72), Mechanical Hemolysis (ASTM F756-17) and expiration date (ASTM F1980)).

The ELISIO™-HX clinical study evaluated the safety and effectiveness of the ELISIO™-HX in adult patients with chronic kidney disease who are suitable candidates for high-flux hemodialysis (HD). The primary safety endpoint was the change in serum albumin level (66 kDa) from baseline to 12 weeks post-treatment. The primary efficacy endpoint was the change in reduction ratio of post-dialysis lambda free light chains (λ-FLC) from baseline to 12 weeks post-treatment. Secondary efficacy endpoints included the reduction ratio of other middle molecules and Kt/V. Secondary safety endpoints included changes in Factor VII, Protein C, Vitamin A and nPNA (nPCR), and laboratory assessments (Comprehensive Metabolic Panel, Hematology Panel). All adverse events, regardless of their relationship to the study device or procedure, were recorded during the study.

The study screened 22 participants at a single site in the United States between September and December 2025. A total of 18 participants underwent a baseline HD treatment with their regular ELISIO™-H dialyzer followed by treatment with the ELISIO™-HX three times a week over a period of 12 weeks. Of the 18 participants, the mean age was 55.5±13.01 years, 55.6% (10/18) were men, 72.2% (13/18) were Black or African American, with mean time on renal replacement therapy of 5.7±5.52 years. Thirteen participants completed all 36 study treatment visits.

Serum albumin levels remained stable from baseline to 12 weeks. The mean level of serum albumin was 4.44±0.355 g/dL at baseline and 4.37±0.534 g/dL at 12 weeks, representing a mean change from baseline of -0.04±0.419 g/dL (95% CI: -0.29, 0.21). Clinical laboratory assessments of coagulation factors, Vitamin A levels, comprehensive metabolic panel and hematology results, as well as nPNA (nPCR) evaluations, revealed no safety concerns associated with ELISIO™-HX. Any changes observed were within expected levels for this patient population and not deemed clinically significant.

The reduction ratio of λ-FLC from baseline to 12 weeks was -11.20% (95% CI: -20.41%, -1.99%) indicating improved removal of λ-FLC after treatment with ELISIO™-HX over baseline treatment with ELISIO™-H. After 12 weeks of treatment with ELISIO™-HX, secondary endpoints showed trends toward increased clearance of TNFα, Complement Factor D, κ-FLC, and β2-Microglobulin compared to ELISIO™-H, but not IL-6 or myoglobin. Single-pool Kt/V was assessed every 4 weeks and remained consistent throughout the study treatment period.

A total of 13 participants experienced 38 Adverse Events (AEs). There were four participants who experienced at least one Serious Adverse Event (SAE), however none of the events were deemed related to the study device or procedure. Eight participants reported experiencing at least one procedure-related AE, most commonly muscle spasms and hypotension events. There were no device-related AEs and no Unanticipated Adverse Device Effects (UADEs). Most AEs were mild or moderate in severity. All adverse events were resolved. Treatment-related adverse events were as expected and consistent with those observed in patients with chronic kidney disease undergoing maintenance hemodialysis. Monthly water and dialysate quality monitoring showed acceptable levels of endotoxin and microbial counts for all samples tested.

Non-clinical performance testing demonstrated that the ELISIO™-HX consistently met its intended performance characteristics across the full range of evaluated membrane surface areas and operating conditions. The device exhibited robust structural integrity, effective and predictable clearance of small and middle molecular weight solutes, controlled solute permeability with strong albumin retention, stable ultrafiltration behavior, and acceptable flow-dependent pressure performance. Clearance and sieving results showed reproducibility and repeatability, and all measurements met predefined acceptance criteria. Clinical data shows hemodialysis treatment with ELISIO™-HX provides improved removal of middle molecules as represented by λ-FLC while maintaining serum albumin levels. These results suggest that hemodialysis using ELISIO™-HX dialyzers can have a persistent effect (i.e. net removal) on the serum levels of some middle molecules that can accumulate in ESRD. Collectively, the performance data confirm that ELISIO™-HX performs as intended without identifying new safety or effectiveness concerns.