March 19, 2026

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

Re: K260533
Trade/Device Name: Elisio™-h
Regulation Number: 21 CFR 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: Class II
Product Code: KDI
Dated: February 19, 2026
Received: February 19, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260533

Device Name
ELISIO™-H

Indications for Use *(Describe)*
ELISIO™-H dialyzers are intended for hemodialysis, hemodiafiltration, hemofiltration, and isolated ultrafiltration in patients with acute kidney injury or chronic kidney disease when conservative therapy is judged to be inadequate.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary - ELISIO™-H

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
Applicant Contact Email	Jessicao@nipromed.com
Preparation Date	March 13, 2026

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

Device Trade Name	ELISIO™-H
Common Name	High permeability hemodialysis system
Classification Name	Dialyzer, High Permeability With Or Without Sealed Dialysate System
Regulation Number	876.5860

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

K131935, ELISIO™-H, Product Code KDI
K140191, ELISIO™-H, Product Code KDI
K203062, Optiflux, Product Code KDI

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

The ELISIO™-H is a single-use, high-flux hemodialyzer intended for the extracorporeal treatment of patients with renal failure. The device is constructed of a plastic cylindrical housing comprised of two compartments, one for blood and one for dialysate, separated by a semi-permeable membrane. Blood is circulated through the blood compartment, while dialysate flows counter currently through the dialysate compartment. This flow pattern enables the removal of uremic toxins, excess fluid, and electrolytes via diffusion and/or convection, depending on the selected treatment modality.

The dialyzer interfaces with the patient via an ISO 8637 compliant blood tubing set and must be used with dialysis machines equipped with an ultrafiltration controller or accurate fluid balancing system. The ELISIO™-H features the POLYNEPHRON™ membrane (Polyethersulfone), for high clearance efficiency and a polypropylene housing not made with BPA or DEHP.

The device is available in eight sizes (surface area): 0.9, 1.1, 1.3, 1.5, 1.7, 1.9, 2.1, and 2.5 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))
ELISIO™-H dialyzers are intended for hemodialysis, hemodiafiltration, hemofiltration, and isolated ultrafiltration in patients with acute kidney injury or chronic kidney disease when conservative therapy is judged to be inadequate.

Indications for Use Comparison (21 CFR 807.92(a)(5))
The subject device Indications for Use are expanded to include HDF, HF and ISO-UF from the currently cleared ELISIO™-H (K131935 and K140191) and identical to the secondary predicate, Optiflux (K203062).

Technological Comparison (21 CFR 807.92(a)(6))
The subject device is identical in design, materials, manufacturing processes, sterilization method, shelf life, packaging and performance specifications to the currently cleared ELISIO™-H (K131935 and K140191). Compared to the secondary predicate, Optiflux, the ELISIO™ H demonstrates equivalent high flux membrane performance and comparable solute transport, permeability, and operating characteristics in HDF modality, confirming that both devices share the same fundamental technological characteristics.

Non-Clinical and/or Clinical Tests Summary & Conclusions (21 CFR 807.92(b))
Performance testing was conducted according to ISO 8637-1: 2024 - 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; Sieving coefficients: albumin, inulin, and β2-microglobulin or myoglobin; Ultrafiltration rate; Ultrafiltration coefficient; Blood compartment volume; Pressure drop; Endotoxin transfer (ANSI/AAMI ST72) and expiration date (ASTM F1980)).

No clinical testing was conducted for this submission.

Performance testing demonstrated that the ELISIO™-H hemodialyzer performs comparably to the predicate device with respect to solute clearance, membrane selectivity, and overall permeability. Hydraulic evaluations confirmed consistent high-flux performance and appropriate pressure characteristics, with no evidence of excessive permeability or protein loss. Materials are identical to those previously reviewed, and therefore no new materials-related risks were introduced. Collectively, the performance data demonstrate that the ELISIO™-H maintains the same intended use and fundamental technological characteristics as the predicate and supports a determination of substantial equivalence.