August 19, 2026

Nipro Technical Solutions, Incoporated
Jessica Oswald-Mcleod
Director, Regulatory Affairs
3110 N Oakland, Suite 101
Mesa, AZ 85215

Re: K260799
Trade/Device Name: Nipro Dry Acid Concentrate Mixer
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: KPO
Dated: July 21, 2026
Received: July 21, 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.	K260799

Please provide the device trade name(s).

Nipro Dry Acid Concentrate Mixer

Please provide your Indications for Use below.

The Nipro Dry Acid Concentrate Mixer is intended for the mixing of dry acid concentrate with treated water that meets the requirements of ISO 23500-3, “Preparation and quality management of fluids for hemodialysis and related therapies—Part 3: Water for hemodialysis and related therapies” to produce an acid concentrate solution intended for use in hemodialysis treatment and related therapies, using a 3-stream dialysate (acid concentrate, bicarbonate concentrate, and water).

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) #: K260799

510(k) Summary

Prepared on: 2026-07-21

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Nipro Technical Solutions, Incoporated
Applicant Address	3110 N. Oakland, Suite 101 Mesa AZ 85215 United States
Applicant Contact Telephone	305-432-6699
Applicant Contact	Mrs. Jessica Oswald-McLeod
Applicant Contact Email	JessicaO@nipromed.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Nipro Dry Acid Concentrate Mixer
Regulation Name	Hemodialysis system and accessories
Classification Name	Dialysate Concentrate For Hemodialysis (Liquid Or Powder)
Regulation Number	876.5820
Product Code(s)	KPO

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K983618	Dri-Sate Mixer for Preparation of Acidified Dialysate Concentrate	KPO
K191093	Isopure Dry Acid Dissolution System	KPO
K223431	Nipro Citric Complete Liquid Citric Acid Concentrate	KPO

Device Description Summary

21 CFR 807.92(a)(4)

The Nipro Dry Acid Concentrate Mixer (Model NACM 50) is designed to combine dry acid concentrate with hemodialysis grade reverse osmosis (RO) water to produce an acid concentrate solution for use in hemodialysis and related renal replacement therapies. The system integrates mechanical, hydraulic, and electronic components to ensure repeatable and reproducible mixing performance. A 50 gallon HDPE mixing tank, paired with a high flow recirculation pump and dual opposing Venturi eductors, creates high turbulence flow that enhances dissolution efficiency and batch homogeneity.

The Control Console enables user operation of all functional modes. The device's performance related functions include Fill (Pre-Fill and Final-Fill) and Pump (Mix, Clean/Rinse, and Transfer).

The Nipro Dry Acid Concentrate Mixer performs a controlled mixing process but does not perform any analytical measurement or acceptance determination of the resulting solution; the dialysis facility is responsible for verifying that the incoming RO water meets applicable quality requirements and for confirming the final mixed solution meets the dry acid manufacturer's acceptance criteria prior to clinical use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Nipro Dry Acid Concentrate Mixer is intended for the mixing of dry acid concentrate with treated water that meets the requirements of ISO 23500-3, "Preparation and quality management of fluids for hemodialysis and related therapies—Part 3: Water for hemodialysis and related therapies" to produce an acid concentrate solution intended for use in hemodialysis treatment and related therapies, using a

3-stream dialysate (acid concentrate, bicarbonate concentrate, and water)

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device, predicate device Dri-Sate Mixer (K983618), and reference device Isopure (K191093) are all dissolution systems intended to produce liquid acid concentrate, one component in a three-stream dialysate used in hemodialysis treatment. No significant differences were identified in the intended use that would introduce new risks.

Nipro Citric Complete (K223431) is included as a reference device for biocompatibility and performance test alignment. This device is appropriate for comparison due to its formulation, handling, and clinical application context directly relevant to the biological endpoints and acid solution composition associated with the output of the subject device, an acid concentrate solution.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device exhibits technological characteristics that are substantially equivalent to those of the predicate device, including intended use, use environment, system architecture, materials of construction, operational principles, and energy sources. The Nipro Dry Acid Concentrate Mixer employs the same fundamental dissolution and mixing technology used to prepare liquid acid concentrate for three-stream dialysate. Performance testing verifies that the device consistently produces liquid acid concentrate meeting the specifications of ANSI/AAMI/ISO 23500-4:2024, demonstrating that its technological features function as intended.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Bench performance testing was conducted by operating the Acid Mixer according to its intended use and labeling, followed by analytical evaluation of the resulting liquid acid solution. The testing strategy was designed to demonstrate repeatable and reproducible performance of the device across representative concentrate formulations, multiple lots, multiple batches, and multiple operators. Specific gravity and temperature were selected as clinically relevant acceptance parameters, as routine dialysis practice relies on measurement and documentation of these parameters to determine batch acceptability in accordance with the concentrate manufacturer specifications.

No clinical testing was performed.

System validation, including human factors/usability engineering, confirmed that the device is safe and effective when considering its intended use, users and use environment. The primary testing objectives for the Acid Mixer system are to verify that the device is correctly installed, calibrated, and capable of consistently producing liquid acid concentrate that meets all required performance, safety, and regulatory specifications. This includes confirming that installation conditions, utilities, safety systems, and device controls function as intended under both normal and stressed operating scenarios, ensuring the system can safely power, fill, mix, pump, drain, and respond to fault conditions such as dry pump operation and sensor disconnections. The data further aims to demonstrate that the Acid Mixer can repeatedly achieve the required critical quality attributes of the final liquid acid concentrate (specific gravity, electrolyte composition, and endotoxin levels) across multiple units and batch repetitions, using acceptance criteria derived from the acid manufacturer and ISO 23500 4:2024.