May 15, 2025

Nikkiso Co., LTD.
% Fumiaki Kanai
President
MIC International
4-32-16 Ryogoku
Sumida-ku, Tokyo 130-0026
Japan

Re: K242479
Trade/Device Name: BLOOD TUBING LINES FOR HEMODIALYSIS AL Series (Archloop)
BLOOD TUBING LINES FOR HEMODIALYSIS C18 Series (AL-ADC-PU, AL-CDC-PU, C18RDC-PU, C18BDD-PU, C18SFD-PU)
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: KOC
Dated: April 14, 2025
Received: April 14, 2025

Dear Fumiaki Kanai:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.	K242479

Please provide the device trade name(s).

BLOOD TUBING LINES FOR HEMODIALYSIS AL Series (Archloop)
BLOOD TUBING LINES FOR HEMODIALYSIS C18 Series (AL-ADC-PU, AL-CDC-PU, C18RDC-PU, C18BDD-PU, C18SFD-PU)

Please provide your Indications for Use below.

This device is indicated for hemodialysis prescribed by physicians for adult patients with acute and chronic renal failure, treated in hospitals and dialysis clinics by qualified operators. This device is not indicated for pediatric patients. It is not for home use.

This device is made up of disposable bloodlines intended to provide extracorporeal access to a patient's blood during hemodialysis. It is the responsibility of the physician or other licensed practitioner to ensure compatibility with the available configurations.

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

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

510(k) Summary

510(k) Number	K242479
Preparation Date	April 11, 2025
Submitter	NIKKISO CO., LTD. 20-3, Ebisu 4-Chome, Shibuya-ku Tokyo 150-6022, Japan
Primary Contact	Satoko Hina Regulatory Affairs Department Medical Division NIKKISO CO., LTD. 20-3, Ebisu 4-Chome, Shibuya-ku Tokyo 150-6022, Japan Phone: +81-3-3443-3754 Fax: +81-3-3473-4965 Email: MedicalRA@nikkiso.co.jp
Subject Device	Device Name: BLOOD TUBING LINES FOR HEMODIALYSIS AL Series (Archloop) BLOOD TUBING LINES FOR HEMODIALYSIS C18 Series (AL-ADC-PU, AL-CDC-PU, C18RDC-PU, C18BDD-PU, C18SFD-PU) Device Classification Name: Accessories, Blood Circuit, Hemodialysis Regulation Number: 21 CFR 876.5820 Regulation Description: Hemodialysis system and accessories Device Class: Class II Classification Product Code: KOC Regulation Medical Specialty: Gastroenterology/Urology 510(k) Review Panel: Gastroenterology/Urology
Device Description	The BLOOD TUBING LINES FOR HEMODIALYSIS AL series (Sterilized by Steam) includes arterial and venous dialysis blood tubing. The devices are packaged together for convenient use during hemodialysis procedures. They are manufactured for application with the DBB-06 PRO Hemodialysis Delivery System. The components of the device include tubing, drip chambers, infusion tubing, pressure monitoring lines, ports, clamps and filters which are used to pump blood, retain and capture blood debris, infuse medications or fluids, sample blood as well as monitor pressure. The devices are packaged sterile and labeled for single use only. These devices cannot be cleaned and reused. They are restricted for sale by or on the order of a physician. The BLOOD TUBING LINES FOR HEMODIALYSIS C18 series is one part of a blood tubing lines for hemodialysis. The devices are packaged together for convenient use during hemodialysis procedures. They are manufactured for application with the DBB-06 PRO Hemodialysis Delivery System. The devices are packaged sterile and labeled for single use only. These devices cannot be cleaned or reused. They are restricted for sale by or on the order of a physician.
Intended Use / Indications for Use	This device is indicated for hemodialysis prescribed by physicians for adult patients with acute and chronic renal failure, treated in hospitals and dialysis clinics by qualified operators. This device is not indicated for pediatric patients. It is not for home use. This device is made up of disposable bloodlines intended to provide extracorporeal access to a patient's blood during hemodialysis. It is the responsibility of the physician or other licensed practitioner to ensure compatibility with the available configurations.

Predicate Device	510(k) Number: Device Name: Applicant: Device Classification Name: Hemodialysis Regulation Number: Regulation Description: Device Class: Classification Product Code: Regulation Medical Specialty: 510(k) Review Panel:	K230514 BLOOD TUBING LINES FOR HEMODIALYSIS AL Series (Archloop) BLOOD TUBING LINES FOR HEMODIALYSIS C18 Series NIKKISO CO. LTD. Accessories, Blood Circuit, 21 CFR 876.5820 Hemodialysis system and accessories Class II KOC Gastroenterology/Urology Gastroenterology/Urology
Technological Characteristics	The Subject Device and Predicate Device have substantially equivalent technological characteristics: • Same Intended Use • Same design and configuration • Same scientific technology and principles of operation The Subject Device differs from the Predicate Device in two respects: • Hemodialysis Delivery System for Subject Device • Sterilization method • Material for Subject Device The Subject Device does not contain any new materials compared to the Predicate Device. Materials included in the Subject Device are as follows: This device is made primarily of polyvinyl chloride (plasticizer DEHP). Materials with direct or indirect contact with blood: Polyvinylchloride (PVC) Polycarbonate (PC) Polypropylene (PP) Silicone rubber (SR) Polytetrafluoroethylene (PTFE) Styrenic thermoplastic elastomer (alias is SEBS: Styrene/Ethylene-Butylene/Styrene) Materials included in the Predicate Device are as follows: This device is made primarily of polyvinyl chloride (plasticizer DEHP). Materials with direct or indirect contact with blood: Methyl Methacrylate Acrylonitrile Butadiene Styrene (MABS) Polyvinylchloride (PVC) Polycarbonate (PC) Polypropylene (PP) Silicone rubber (SR) Polytetrafluoroethylene (PTFE) Styrenic thermoplastic elastomer (alias is SEBS: Styrene/Ethylene-Butylene/Styrene) Isoprene rubber (IR)	

FDA Guidance Documents	The following FDA guidance documents were referenced in preparing this premarket notification: • Electronic Submission Template for Medical Device 510(k) Submissions Guidance for Industry and Food and Drug Administration Staff October 2023 • Format for Traditional and Abbreviated 510(k)s, issued September 2019 • Guidance for Industry: Pyrogen and Endotoxins Testing: Questions and Answers, issued June 2012 • Hemodialysis Blood Tubing Sets, issued April 2008 • Labeling: Regulatory Requirements for Medical Devices, issued August 1989 • Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions, issued December 2019 • Shelf Life of Medical Devices, issued April 1991 • Submission and Review of Sterility Information in Premarket Notification (510(k)) • Submissions for Devices Labeled as Sterile, issued January 2016 • Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", issued June 2016
Sterilization and Shelf Life	Sterilization validation and shelf life testing was completed using the subject device BLOOD TUBING LINES FOR HEMODIALYSIS AL Series
Biological Safety	Biological safety testing was completed to confirm the safety of the subject device: • Cytotoxicity Unaged • Cytotoxicity Aged • Sensitization • Intracutaneous Reactivity • Acute Systemic Toxicity • Pyrogenicity • Subchronic Systemic Toxicity • Genotoxicity BRM • Genotoxicity MLA • Hemocompatibility Hemolysis Unaged • Hemocompatibility Hemolysis Aged • Hemocompatibility Complement Activation • Hemocompatibility Thrombogenicity • Hemocompatibility Thrombogenicity • Hemocompatibility Mechanical Hemolysis • Chemical Characterization • Extractable Analysis • Biological Risk Assessment

Performance - Bench	Bench testing was completed to confirm the subject device is substantially equivalent to the predicate device in performance: • Structural Integrity • Pump Segment Performance • Needle Access Ports • Needleless Access Ports • Blood Pathway Volume • Tensile Strength • Transducer Protectors • Tubing Compliance • Mechanical Hemolysis • Resist Kinking After Repeated Clamping • Simulated Treatment • Connector to Haemodialyser • Connectors to Vascular Access Device • Connectors to Ancillary Components • Colour Coding • Air-Capture Chamber Fill Level • Blood Pathway Flow Dynamics
Performance - Animal	No animal performance data is submitted in this 510(k).
Performance - Clinical	No clinical performance data is submitted in this 510(k).
Substantial Equivalence	The Subject Device has the same intended use as the Predicate Device. The Subject Device has the same design and configuration as the Predicate Device. The scientific technology and principles of operation are the same between the Subject Device and the Predicate Device. Materials used for the Subject Device and the Predicate Device are similar and no new or additional materials are used in the Subject Device other than materials used in the Predicate Device. The dialysis machine model, sterilization method and the shape of the connection part of the pressure measurement part used in the Subject Device is different for the Predicate Device. Several performance tests confirmed compatibility of the Subject Device with the dialysis machine as for the Predicate Device. In conclusion, based on the above considerations, the Subject Device does not raise any new questions regarding safety and effectiveness, and the Subject Device is substantially equivalent to the Predicate Device.
Conclusion	This comparison demonstrates that the Subject Device is substantially equivalent to the predicate device. The Subject Device is as safe and effective as the predicate device and will perform as intended.