June 16, 2023

NIKKISO Co., Ltd.
Fumiaki Kanai
President & CEO
MIC International
4-32-16 Ryogoku
Sumida-ku, Tokyo 130-0023
JAPAN

Re: K230514
Trade/Device Name: Blood Tubing Lines for Hemodialysis AL Series (Archloop);
AL-ADC-E(U)06, AL-CDC-E(U)06
Blood Tubing Lines for Hemodialysis C18 Series;
C18BDD-E(U)06, C18RDC-E(U)06, C18SFD-E(U)06
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: Class II
Product Code: KOC
Dated: June 5, 2023
Received: June 7, 2023

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Gema Gonzalez -S

Gema Gonzalez, MS
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230514

Device Name
BLOOD TUBING LINES FOR HEMODIALYSIS AL Series (Archloop)
BLOOD TUBING LINES FOR HEMODIALYSIS C18 Series

Indications for Use *(Describe)*
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.

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.

5. 510(k) Summary

510(k) Number	K230514
Preparation Date	June 15th, 2023
Submitter	NIKKISO CO., LTD. 20-3, Ebisu 4-Chome, Shibuya-ku Tokyo 150-6022, Japan
Contact	Satoko Hina Quality Assurance 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 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 (Archloop) 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 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 or 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 device for hemodialysis. The devices are packaged together for convenient use during hemodialysis procedures. They are manufactured for application with the DBB-06 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: Regulation Number: Regulation Description: Device Class: Classification Product Code: Regulation Medical Specialty: 510(k) Review Panel:	K082719 NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS, MODELS AV06A-P, AV06B-P, AV06C-P NIKKISO CO., LTD. Accessories, Blood Circuit, Hemodialysis 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: • Similar intended use including similar indication for use. • Similar design and configuration. • Same scientific technology and principles of operation. The following are the only minor differences: • EOG sterilization is adopted as the sterilization method. • Newly adopted Styrenic thermoplastic elastomer (SEBS), Isoprene rubber (IR) and Methyl Methacrylate Acrylonitrile Butadiene Styrene (MABS) as new materials. • In addition to traditional transducer protection filters, PODs (Pressure monitor pod) are used as a connection component to the pressure measurement unit. • Compliance with the latest standards and guidance.	
FDA Guidance Documents	The following FDA guidance documents were referenced in preparing this premarket notification: • *eCopy Program for Medical Device Submissions*, issued April 2020 • *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	

Performance - Bench	Bench testing was completed to confirm that the subject device is substantially equivalent in performance. A summary of the performance tests is included in Appendix 23 Evaluation of EOG Sterile AL and C18 series for DBB-06. The following 20 performance tests were performed.

No.	Test Item	Report
1	Sterilization Barrier System Performance Test	TR-20210412-070442-16 (Appendix 24)
2	Blood Pathway Flow Dynamics	TR-20210331-070442-01 (Appendix 25)
3	Colour Coding	VER-P301201-160 (Appendix 26)
4	Connectors to Haemodialyser	TR-20210412-070442-02 (Appendix 27)
5	Connectors to Ancillary Components	TR-20210412-070442-15 (Appendix 28)
6	Connectors to Vascular Access Device	TR-20210412-070442-03 (Appendix 29)
7	Mechanical Hemolysis	TR-20210412-070442-11 (Appendix 30)
8	Needle Access Ports	TR-20210412-070442-04 (Appendix 31)
9	Needleless Access Ports	TR-20210412-070442-05 (Appendix 32)
10	Blood Pathway Volume	TR-20210412-070442-06 (Appendix 33)
11	Structural Integrity	TR-20210412-070442-01 (Appendix 34)
12	Tensile Strength	TR-20210412-070442-13 (Appendix 35)
13	Transducer Protectors	TR-20210412-070442-10 (Appendix 36)
14	Dimensional and Workmanship Analysis	TR-20211101-070442-01 (Appendix 37)
15	Peak Pressure Test of EOG Sterile AL Series for DBB-06	TR-20230104-070442-01 (Appendix 38)
16	Pump Segment Performance	TR-20221222-070442-01 (Appendix 39)
17	Air-capture Chamber Fill Level	TR-20220707-210531-03 (Appendix 40)
18	Resist Kinking After Repeated Clamping	TR-20220707-210531-02 (Appendix 41)
19	Tubing Compliance	TR-20220707-210531-01 (Appendix 42)
20	Simulated Treatment	TR-20230523-070442-01 (Appendix 43)

Performance- Animal	No animal performance data is submitted in this Traditional 510(k).
Performance-Clinical	No clinical performance data is submitted in this Traditional 510(k).
Substantial Equivalence	The subject devices are substantially equivalent to the predicate device when evaluating intended use and technological characteristics. • The subject devices have the same intended use as the predicate device. • The subject devices and predicate device are substantially equivalent with only minor technological differences. • These differences do not raise new questions of safety and effectiveness.
Conclusion	This comparison demonstrates that the subject devices are substantially equivalent to the predicate device. The subject devices are as safe and effective as the predicate device and will perform as intended.