July 28, 2023

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

Re: K231589
Trade/Device Name: Blood Tubing Lines for Hemodialysis AV06C-E
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: Class II
Product Code: KOC
Dated: May 26, 2023
Received: June 1, 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

3. Indications for Use Statement

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)*

K231589

Device Name

BLOOD TUBING LINES FOR HEMODIALYSIS AV06C-E

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.

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

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5. 510(k) Summary

510(k) Number	TBD
Preparation Date	May 26, 2023
Submitter	NIKKISO CO., LTD. 20-3, Ebisu 4-Chome, Shibuya-ku Tokyo 150-6022, Japan
Primary 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 AV06C-E 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 AV06C-E 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 and 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.

510(k) Summary (continued)

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:	K082719 NIKKLINE BLOOD TUBING LINES WITH TRANSDUCER PROTECTORS, MODELS AV06A-P, AV06B-P, AV06C-P 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: • Similar intended use including similar indication for use • Similar design and configuration • Same scientific technology and principles of operation The followings are only minor differences: • EOG sterilization is adopted as the sterilization method • 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	
Sterilization and Shelf Life	Sterilization validation and Shelf Life test were completed using the subject device BLOOD TUBING LINES FOR HEMODIALYSIS AV06C-E. Appendix 4 Sterilization Barrier System Performance Test AV06C-E	

510(k) Summary (continued)

Biological Safety	Biological safety testing was completed to confirm the safety of the subject device: • Appendix 5 Cytotoxicity Unaged • Appendix 6 Cytotoxicity Aged • Appendix 7 Sensitization • Appendix 8 Intracutaneous Reactivity • Appendix 9 Acute Systemic Toxicity • Appendix 10 Pyrogenicity • Appendix 11 Subchronic Systemic Toxicity • Appendix 12 Genotoxicity BRM • Appendix 13 Genotoxicity MLA • Appendix 14 Hemocompatibility Hemolysis Unaged • Appendix 15 Hemocompatibility Hemolysis Aged • Appendix 16 Hemocompatibility Complement Activation • Appendix 17 Hemocompatibility Thrombogenicity 1 • Appendix 18 Hemocompatibility Thrombogenicity 2 • Appendix 19 Hemocompatibility Mechanical Hemolysis • Appendix 20 Hemocompatibility Platelet and leukocyte count assay • Appendix 21 Chemical Characterization • Appendix 22 Degradation Test • Appendix 23 Biological Risk Assessment • Appendix 24 Cited Document of Biological Risk Assessment
Performance - Bench	Bench testing was completed to confirm the subject device is substantially equivalent to the predicate device in performance: • Appendix 25 Structural Integrity for AV06C-E • Appendix 26 Pump Segment Performance for AV06C-E • Appendix 27 Needle Access Ports AV06C-E • Appendix 28 Blood Pathway Volume for AV06C-E • Appendix 29 Tensile Strength AV06C-E • Appendix 30 Transducer Protectors AV06C-E • Appendix 31 Tubing Compliance AV06C-E • Appendix 32 Mechanical Hemolysis for AV06C-E • Appendix 33 Resist Kinking After Repeated Clamping for AV06C-E • Appendix 34 Simulated Treatment AV06C-E • Appendix 35 Connector to Haemodialyser AV06C-E • Appendix 36 Connectors to Vascular Access Device AV06C-E • Appendix 37 Connectors to Ancillary Components AV06C-E • Appendix 38 Colour Coding AV06C-E • Appendix 39 Air-Capture Chamber Fill Level for AV06C-E • Appendix 40 Blood Pathway Flow Dynamics AV06C-E
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 is substantially equivalent to the predicate device when evaluating intended use and technological characteristics. • The subject device has the same intended use as the predicate device. • The subject device 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 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.