January 16, 2026

Vital Healthcare Sdn. Bhd.
Ch'ng Hui Zhen
Regulatory Affair
PT 83718, Jalan Bestari 1A/KU7
Taman Perindustrian Kapar Bestari
Kapar, Selangor 42200
Malaysia

Re: K251341
Trade/Device Name: VITAL Tubing Sets for Hemodialysis – Models Models: BLU001E, BLU002E, BLU003E, BLU004E, BLU005E, BLU006E, BLU007E, BLU008E, BLU009E, BLU010E, BLU011E, BLU012E, BLU013E, BLU014E, BLU015E, BLU016E, BLU017E, BLU018E, BLU019E, BLU020E, BLU021E, BLU022E, BLU023E, BLU024E, BLU025E, BLU026E, BLU027E, BLU028E, BLU029E, BLU030E, BLU063E
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: Class II
Product Code: FJK
Dated: December 19, 2025
Received: December 19, 2025

Dear Ch'ng Hui Zhen:

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,

Gema Gonzalez -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)*
K251341

Device Name
VITAL Tubing Sets for Hemodialysis

Indications for Use *(Describe)*
The VITAL Tubing Sets for Hemodialysis are sterile, single-use arterial and venous blood lines for exclusive use with AK98 (model BLU014E, BLU015E, BLU021E, BLU022E, BLU025E), Fresenius 2008 series (model BLU001E, BLU002E, BLU003E, BLU004E, BLU005E, BLU006E, BLU007E, BLU008E, BLU009E, BLU010E, BLU011E, BLU012E, BLU013E, BLU016E, BLU017E, BLU018E, BLU020E, BLU023E, BLU024E, BLU029E, BLU030E, BLU063E), Fresenius 5008X (model BLU026E, BLU027E) or Bbraun Dialog series Hemodialysis system (model BLU019E, BLU028E). The blood lines serve as the extracorporeal blood circuit in patients undergoing hemodialysis treatment, by which blood is transported from the patient through a hemodialyzer and back to the patient. The pump line interfaces with a pump rotor mechanism of the hemodialysis machine which drives the flow of blood through the circuit.

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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Tab #29 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K251341

1. **Date of Preparation:** 16 Jan 2026

2. **Sponsor Identification**

Vital Healthcare Sdn. Bhd.
PT 83718, Jalan Bestari 1A/KU7, Taman Perindustrian Kapar Bestari, 42200 Kapar, Selangor, Malaysia.

Establishment Registration Number: Not Known

Contact Person: Ch'ng Hui Zhen
Position: Regulatory Affair
Tel: +603 33962329
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3. **Designated Submission Correspondent**

Vital Healthcare Sdn. Bhd.
PT 83718, Jalan Bestari 1A/KU7, Taman Perindustrian Kapar Bestari, 42200 Kapar, Selangor, Malaysia.

Ms. Ch'ng Hui Zhen (Primary Contact Person)
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4. Identification of Proposed Device

Trade Name: VITAL Tubing Sets for Hemodialysis

Common Name: Haemodialysis tubing set

Models: BLU001E, BLU002E, BLU003E, BLU004E, BLU005E, BLU006E, BLU007E, BLU008E, BLU009E, BLU010E, BLU011E, BLU012E, BLU013E, BLU014E, BLU015E, BLU016E, BLU017E, BLU018E, BLU019E, BLU020E, BLU021E, BLU022E, BLU023E, BLU024E, BLU025E, BLU026E, BLU027E, BLU028E, BLU029E, BLU030E, BLU063E

Regulatory Information

Classification Name: Set, Tubing, Blood, With and Without Anti-Regurgitation Valve

Classification: II

Product Code: FJK

Regulation Number: CFR876.5820

Review Panel: Gastroenterology/Urology

Indications for use:

The VITAL Tubing Sets for Hemodialysis are sterile, single-use arterial and venous blood lines for exclusive use with AK98 (model BLU014E, BLU015E, BLU021E, BLU022E, BLU025E), Fresenius 2008 series (model BLU001E, BLU002E, BLU003E, BLU004E, BLU005E, BLU006E, BLU007E, BLU008E, BLU009E, BLU010E, BLU011E, BLU012E, BLU013E, BLU016E, BLU017E, BLU018E, BLU020E, BLU023E, BLU024E, BLU029E, BLU030E, BLU063E), Fresenius 5008X (model BLU026E, BLU027E) or Bbraun Dialog series Hemodialysis system (model BLU019E, BLU028E). The blood lines serve as the extracorporeal blood circuit in patients undergoing hemodialysis treatment, by which blood is transported from the patient through a hemodialyzer and back to the patient. The pump line interfaces with a pump rotor mechanism of the hemodialysis machine which drives the flow of blood through the circuit.

Device Description

The VITAL Tubing Sets for Hemodialysis consists of an Arterial line and a Venous line. The tubing is soft, transparent, smooth and non-kink to ensure the good liquidity.

The proposed models have the same principles, intended use and manufacturing process, but have some difference in the product configuration and dimension. The typical/representative model is BLU063E among all the models due to it has the most complex structure for Ethylene Oxide sterilization which covers all the components of the other models and the distance from the closed end and ventilated end is the farthest.

The proposed devices are provided in sterile condition, it is subject to ethylene oxide sterilization prior

to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

5. Identification of Predicate Device

510(k) Number: K201866
Product Name: NovaLine Tubing Sets for Hemodialysis
Manufacturer: Bain Medical Equipment (Guangzhou) Co., Ltd

6. Non-Clinical Test Conclusion

Non clinical tests, such as performance testing, packaging testing, side by side testing, hemodialysis machine compatibility testing, biocompatibility & chemical analysis were conducted to verify that the proposed device meet all design specifications and is Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IS0 11607-1:2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- IS0 11607-2:2019 Packaging for terminally sterilized medical devices- Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F88/F88M-23 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1929-23 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Device
- ISO 8637-2:2024 Extracorporeal systems for blood purification - Part 2: Extracorporeal blood and fluid circuits for haemodialyzer, haemodiafilters, haemofilter and haemoconcentrators.
- ISO 80369-7:2021 Small bore connectors for liquids and gases in healthcare applications- Part 7: Connectors for intravascular or hypodermic applications
- ASTM D4169-23 Standard Practice For Performance Testing Of Shipping Containers And Systems.
- ASTM F2096-11 (2019) Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- USP <85> Bacterial Endotoxin Test
- EN ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for in vitro Cytotoxicity
- EN ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- EN ISO 10993-10:2021 Biological Evaluation of Medical Devices - Part 10: Tests for Skin Sensitization
- EN ISO 10993-11:2017 Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity

- EN ISO 10993-4:2017 Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood
- EN ISO 10993-6:2016 Biological Evaluation of Medical Devices - Part 6: Tests for local effects after implantation
- EN ISO 10993-7:2008 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
- EN ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process
- EN ISO 10993-17:2023 Biological evaluation of medical devices - Part 17 Toxicological risk assessment of medical device constituents
- EN ISO 10993-18:2020 Biological evaluation of medical devices - Part 18 Chemical characterization of medical device materials within a risk management process

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

The technological differences between the proposed and predicated devices are stated as below.

	Proposed Device	**Predicated Device**	**Remark**
Device Name	VITAL Tubing Sets for Hemodialysis	NovaLine Tubing Sets for Hemodialysis	SE
Indication for Use	The VITAL Tubing Sets for Hemodialysis are sterile, single-use arterial and venous blood lines for exclusive use with AK98 (model BLU014E, BLU015E, BLU021E, BLU022E, BLU025E), Fresenius 2008 series (model BLU001E, BLU002E, BLU003E, BLU004E, BLU005E, BLU006E, BLU007E, BLU008E, BLU009E, BLU010E, BLU011E, BLU012E, BLU013E, BLU016E, BLU017E, BLU018E, BLU020E,	The NovaLine Tubing Sets for Hemodialysis - Models BL 11 and BL 12 - are sterile, single-use arterial and venous blood lines for exclusive use with the Baxter Healthcare AK98 Hemodialysis System. The blood lines serve as the extracorporeal blood circuit in patients undergoing hemodialysis treatment, by which blood is transported from the patient through a hemodialyzer and back to the patient. The pump line interfaces with a pump rotor mechanism of the	Discussion 1

	BLU023E, BLU024E, BLU029E, BLU030E, BLU063E), Fresenius 5008X (model BLU026E, BLU027E) or Bbraun Dialog series Hemodialysis system (model BLU019E, BLU028E). The blood lines serve as the extracorporeal blood circuit in patients undergoing hemodialysis treatment, by which blood is transported from the patient through a hemodialyzer and back to the patient. The pump line interfaces with a pump rotor mechanism of the hemodialysis machine which drives the flow of blood through the circuit.	hemodialysis machine which drives the flow of blood through the circuit.	
Feature	Pre-Pump Post-Pump Color Coded component Sterile Non-pyrogenic Single Use Prescription Device	Pre-Pump Post-Pump Color Coded component Sterile Non-pyrogenic Single Use Prescription Device	SE
Main Configuration	Arterial & Venous Line Drip Chamber Main Tubing Branch Tubing Female Luer Lock Clamps Filters	Arterial & Venous Line Drip Chamber Main Tubing Branch Tubing Female Luer Lock Clamps Filters	SE
Physical Performance	The priming volume (mL/mm) of the proposed devices are as below: BLU063E is 201±10% BLU001E is 130±10% BLU002E is 128±10% BLU003E is 128±10% BLU004E is 144±10% BLU005E is 142±10%	The priming volume (mL/mm) of BL 11 & BL 12 are 127±10% & 186±10% respectively.	Discussion 2

	BLU006E is 156±10% BLU007E is 155±10% BLU008E is 144±10% BLU009E is 142±10% BLU010E is 161±10% BLU011E is 153±10% BLU012E is 156±10% BLU013E is 153±10% BLU014E is 129±10% BLU015E is 187±10% BLU016E is 141±10% BLU017E is 122±10% BLU018E is 132±10% BLU019E is 104±10% BLU020E is 93±10% BLU021E is 127±10% BLU022E is 186±10% BLU023E is 152±10% BLU024E is 124±10% BLU025E is 88±10% BLU026E is 139±10% BLU027E is 142±10% BLU028E is 157±10% BLU029E is 161±10% BLU030E is 103±10%		
	Positive pressure Limitation (mmHg) for all proposed devices is 500.	Positive pressure Limitation (mmHg) is 500.	
	Negative Pressure Limitation (mmHg) for all proposed devices is -500.	Negative Pressure Limitation (mmHg) is -500.	
Performance	Conforms to ISO8637-2:2024 ISO80369-7:2021	Conforms to ISO8638:2010 ISO594-2:1998	Discussion 3
Materials	It consists of various materials, such as PVC, PP, PE, ABS, PC, Silicone rubber, PCTG, PETG, MABS.	It consists of various materials, such as PP, PVC, Silicone rubber, ABS, PE.	Discussion 4
Biocompatibility	Chemical Analysis Conforms to ISO10993 series standards	Conforms to ISO10993 series standards	Discussion 5
Sterilization	By Ethylene Oxide, SAL (10^{-6})	By E-Beam Irradiation, SAL (10^{-6})	Discussion 6

Labelling	Direction for Use Intended Use Description Warnings and Cautions	Direction for Use Intended Use Description Warnings and Cautions	SE

Discussion 1 – Indications for Use

The indication for use of the proposed and predicate device have clearly stated the compatible system to avoid any misuse. The compatibility between the proposed device and the hemodialysis system is included in this submission. Both of them are still used for the same purpose, which is to connect with a hemodialysis system and provide extracorporeal access to the patient's blood during hemodialysis. This difference will not result in any safety and effectiveness issue of the proposed device.

Discussion 2 – Physical Performance

The priming volume of the proposed and predicate device is different due to their length of main tubes is different. Differences in the tubing length and priming volume can impact the mechanical and performance characteristics of device. The bench tests such as pressure leak test, endurance testing, priming volume test, tensile strength test, tube kinking inspection, blood pump segment validation were conducted to prove that the proposed device meet the requirements of mechanical and performance characteristics. Therefore, the differences in priming volume will not lead to new safety and effectiveness problems.

Discussion 3 - Performance

The ISO standard of the predicate device, ISO8638-2010 has been withdrawn and replaced with ISO8637-2, whereas ISO594-2 has also been replaced with ISO80369-7. Updated ISO version will not lead to new safety and effectiveness issue in the proposed device.

Discussion 4 – Material

The material of the proposed device is PVC, PP, PE, ABS, PC, Silicone rubber, PCTG, PETG, MABS. These materials of proposed device have many years of clinical application history and are non-innovative materials. We have conducted chemical analysis and biocompatibility tests according to the requirements of ISO10993 series, and the results were all passed. Therefore, we think the differences on the materials will not cause new problems on the safety and effectiveness.

Discussion 5 - Biocompatibility

Chemical analysis according to ISO 10993-17 and ISO 10993-18 that supports the biocompatibility of the proposed device is included in this submission. The biocompatibility studies that carried out in the proposed device are also complied with ISO 10993 series standards. Therefore, this item is considered substantially equivalent.

Discussion 6 –Sterilization Method

The sterilization method of the proposed device is Ethylene Oxide sterilization. The sterilization method of the predicate device is E-Beam sterilization. Both of the sterilization assurance level can reach 10^{-6}. This difference will not result in any safety and effectiveness issue of the proposed device.

Conclusion:

According to the analysis in Substantially Equivalent Discussion, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices. Their differences will not result in new safety and effectiveness issue in the proposed device.