May 15, 2026

Bain Medical Equipment(Guangzhou) Co., Ltd.
Zoe Zeng
Regulatory Affair Supervisor
No.10, Juncheng Road, Eastern Area,
Economic and Technological Development
Guangzhou, 510760
China

Re: K252423
Trade/Device Name: NovaLine Tubing Set for Hemodialysis (BL 124)
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis System And Accessories
Regulatory Class: Class II
Product Code: FJK
Dated: April 15, 2026
Received: April 15, 2026

Dear Zoe Zeng:

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.	K252423

Please provide the device trade name(s).

NovaLine Tubing Set for Hemodialysis (BL 124)

Please provide your Indications for Use below.

The NovaLine Tubing Set for Hemodialysis – BL 124 – is sterile, single-use arterial and venous blood line for exclusive use with the Vantive AK 98 delivery System. The bloodline serves 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.

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)

024_Update 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: K252423

1. **Date of Preparation:** April 10, 2026

2. **Sponsor Identification**

Bain Medical Equipment (Guangzhou) Co., Ltd.
No.10, Juncheng Road, Eastern Area, Economic and Technological Development, 510760, Guangdong, P.R.China

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3. **Designated Submission Correspondent**

Bain Medical Equipment (Guangzhou) Co., Ltd.
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4. Identification of Proposed Device

Trade Name: NovaLine Tubing Set for Hemodialysis

Common Name: Hemodialysis Tubing Set

Models: BL 124

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 NovaLine Tubing Set for Hemodialysis – BL 124 – is sterile, single-use arterial and venous blood line for exclusive use with the Vantive AK 98 delivery System. The bloodline serves 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 NovaLine 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 devices are provided in sterile condition, it is subject to e-beam sterilization prior to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

The choice of the proper dialyzer and blood line set is the responsibility of the physician in charge. When selecting bloodline set for a treatment, the total extracorporeal blood volume (i.e. the dialyzer, the bloodline set and any other accessories combined) shall not exceed 10% of the patient's blood volume.

5. Identification of Predicate Device

510(k) Number: K201866

Product Name: NovaLine Tubing Sets for Hemodialysis - Models BL11 and BL12

Manufacturer: Bain Medical Equipment (Guangzhou) Co., Ltd

6. Non-Clinical Test Conclusion

Non clinical tests, such as performance testing, side by side testing, mechanical hemolysis testing and hemodialysis machine compatibility testing 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:

- 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

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Technological Characteristic	**Proposed Device K252423**	**Predicate Device K201866**	**Remark**
Device Class	II	II	SE
Product Code	FJK	FJK	SE
Regulation Number	21CFR part 876.5820	21CFR part 876.5820	SE
Indications for Use	The NovaLine Tubing Set for Hemodialysis – BL 124 – is sterile, single-use arterial and venous blood lines for exclusive use with the Vantive AK 98 delivery System. The bloodline serves 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 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 hemodialysis machine which drives the flow of blood through the circuit.	SE

Technological Characteristic		Proposed Device K252423	Predicate Device K201866	Remark
		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		Drip Chamber	Drip Chamber	Discussion 1
		Main Tubing	Main Tubing	
		Branch Tubing	Branch Tubing	
		Female Luer Lock	Female Luer Lock	
		Clamps	Clamps	
		Filters	Filters	
		Venous Line	Venous Line	
		Main Tubing	Main Tubing	
		Branch Tubing	Branch Tubing	
		Female Luer Lock	Female Luer Lock	
		Clamps	Clamps	
		Filters	Filters	
Physical performance	**Priming Volume (mL/mm)**	BL 124: 88±10% ml	BL 12: 186±10% ml	Discussion 2
	Positive pressure Limitation (mmHg)	500	500	
	Negative Pressure Limitation (mmHg)	-500	-500	
Performance		Conforms to ISO 8637-2:2024 ISO 80369-7:2021	Conforms to ISO8638:2010 ISO594-2:1998	Discussion 3
Materials		The major components of the NovaLine Tubing Sets for Hemodialysis are made from medical-grade PVC, PP, PC, ABS, PE and other medical-grade macromolecule	The major components of the NovaLine Tubing Sets for Hemodialysis are made from medical-grade PVC, PP, PC, ABS, PE and other medical-grade macromolecule materials.	Discussion 4

Technological Characteristic	Proposed Device K252423	Predicate Device K201866	Remark
	materials.		
Biocompatibility	Conforms to ISO 10993 series standards	Conforms to ISO 10993 series standards	SE
Sterilization	EBEAM, SAL(10-6)	EBEAM, SAL(10-6)	SE
Labeling	Direction for Use	Direction for Use	SE
	Intended Use	Intended Use	
	Description	Description	
	Warnings and Cautions	Warnings and Cautions	

Discussion 1 – Main Configuration & Discussion 2 – Physical Performance

The proposed device has the similar design of the components with the predicated device. The priming volume of the proposed and predicate device is different due to their length of main tubes is different. Differences in the structure, tubing length and priming volume can impact the mechanical and performance characteristics of device. The side by side bench tests such as pressure leak test, endurance testing, priming volume test, tensile strength test, mechanical hemolysis 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 configuration and 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 – Materials

The proposed device and the predicate device (K201866) utilize the same categories of medical-grade materials (e.g., PVC, PP, PC, ABS, PE) for blood-contacting components. Although the specific raw material model for the main tubing differs, this model has a history of use in the pump segment of the predicate device itself, under identical blood contact conditions. Additionally, the difference in colorant for small clamps is supported by the use of the same material with white colorant in an equivalent component of another legally marketed device (K213015). These differences will not lead to new safety and effectiveness problems.

Based on the comparison and analysis in Substantially Equivalent Discussion, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.