March 10, 2021

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

Re: K201866
Trade/Device Name: NovaLine Tubing Sets for Hemodialysis
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FJK
Dated: February 8, 2021
Received February 9, 2021

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 (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,

Carolyn Y. Neuland, Ph.D.
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)*
K201866

Device Name
Novaline Tubing Sets for Hemodialysis

Indications for Use *(Describe)*
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.

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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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: K201866

1. Date of Preparation: 3/08/2021

2. Sponsor Identification

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3. Designated Submission Correspondent

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510(k) Summary

4. Identification of Proposed Device

Trade Name: NovaLine Tubing Sets for Hemodialysis
Common Name: Blood tubing sets
Models: BL11, BL12

Regulatory Information

Classification Name: Hemodialysis system and accessories
Classification: II
Product Code: FJK
Regulation Number: 876.5820
Review Panel: Gastroenterology/Urology

Indications for Use:
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.

Device Description:
The proposed devices, NovaLine Tubing Sets for Hemodialysis, mainly consists of two tubes, which are arterial line with certain components in red and venous line with certain components in blue, as well as accessory which is recirculating connector.

There are two models BL 11 and BL 12, The main difference between BL 11 and BL 12 is the Drip chamber on the arterial line. There is drip chamber on the arterial line of BL 12, there is no drip chamber on the arterial line of BL 11. The BL 12 has more drip chambers than the BL 11 on the whole tubing.

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.

The proposed devices are provided in sterile condition, it is subject to e-beam radiation sterilization prior to release to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

5. Identification of Predicate Device

Predicate Device
510(k) Number: K161582
Product Name: DORA Tubing Sets for Hemodialysis
Manufacturer: Bain Medical Equipment (Guangzhou) Co., Ltd

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 8638 Third Edition 2010-07-01, Cadiovascular Implants and Extracorporeal Blood Circuit for Hemodialyzers, Hemodialfilters, And Hemofilters. 9-89
- ISO 594-2 Second Edition 1998-09-01, Conical Fittings with A 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment - Part 2: Lock Fittings.
- ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems.
- ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

7. Clinical Test Conclusion

No clinical study is included in this submission.

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8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristic

Item	Proposed Device	Predicate Device K161582
Model	BL 11/ BL 12	BAIN-BL-002E
Device Class	II	II
Product Code	FJK	FJK
Reg. Number	21CFR part 876.5820	21CFR part 876.5820
Indications for Use (Discussion 1)	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.	The DORA Tubing Sets for Hemodialysis are single-use sterile medical devices intended to connect the patient to the hemodialyzer and the hemodialysis delivery system in hemodialysis treatment. The compatibility of available configurations is the responsibility of the physician/clinician in charge.
Compatible hemodialysis delivery system (Discussion 2)	The hemodialysis delivery system which is compatible with the product is AK 98 Hemodialysis System manufactured by Baxter.	The hemodialysis delivery system which is compatible with the product is Fresenius 2008K manufactured by Fresenius Medical Care North America.
Feature	Pre-Pump Post-Pump Color Coded component Sterile Non-pyrogenic Single Use	Pre-Pump Post-Pump Color Coded component Sterile Non-pyrogenic Single Use

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		Prescription Device	Prescription Device
Main Configuration		Arterial Line	Arterial Line
		Venous Line	Venous Line
		Drip Chamber	Drip Chamber
		Branch Lines	Branch Lines;
		Female Luer Lock	Female Luer Lock
		Clamps	Clamps
		Filter	Filters
Accessory (Discussion 3)		Recirculating Connector	Recirculating Connector
		/	Drain Bag
Small Components (Discussion 4)		Dropper Elbow	/
Physical performance (Discussion 5)	Length of arterial line(*mm*)	BL 11: 2890 BL 12: 3290	3500
	Length of venous line(*mm*)	BL 11: 2700 BL 12: 2700	3000
	Priming Volume (mL)	BL 11: 127±10% BL 12: 186±10%	163±10%
	Positive pressure (mmHg)	500	500
	Negative Pressure (mmHg)	-500	-500
	Blood flow rate limitations	600	500
Performance		Conforms to ISO8638:2010 ISO594-2:1998	Conforms to ISO8638:2010 ISO594-2:1998
Materials		Various materials	Various materials
Biocompatibility (Discussion 6)		Conforms to ISO 10993 series standards	Cytotoxicity; Sensitization Intracutaneous reactivity; Acute systemic toxicity; Hemolysis Partial Thromboplastin Time Complement System In vitro Chromosomal Aberration Bacterial Reverse Mutation Mouse Bone Marrow Micronucleus
Sterilization		SAL(10^{-6})	SAL(10^{-6})

510(k) Summary

Labeling	Direction for Use	Direction for Use
	Intended Use	Intended Use
	Description	Description
	Warnings and Cautions	Warnings and Cautions

Discussion 1 – Indications for Use

The intended use of the proposed and predicate device are different in text, however, both of them are used 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 – Compatible hemodialysis delivery system

The compatible system of the proposed device is specified as AK 98 Hemodialysis System, which is a hemodialysis delivery system being submitted to FDA for premarket notification(K201809); the compatible system of the predicate device is Fresenius 2008K. The instructions of the proposed device have clearly stated the compatible system, which will not result in any misuse. Bench testing included in this submission support the compatibility between the proposed device and the compatible system. This difference will not result in any safety and effectiveness issue of the proposed device.

Discussion 3- Accessory

The proposed device and predicate device have the same main configuration, meanwhile they have different components on the details. The predicate device has drain bag for waste collection, while the proposed devices don't have this accessory. No drain bag will not affect the clinical using of the proposed device, therefore, this difference will not raise new problem on the safety and effectiveness.

Discussion 4- Small Components

The proposed device and predicate device are different in small components. The proposed have Dropper and Elbow, however, the predicate device has not the small component. Bench testing included in this submission support the performance of the device. This difference will not result in any safety and effectiveness issue of the proposed device.

Discussion 5- Physical performance

The length of main tubes of proposed device is different to that of the predicate device. The difference on the length of main tubes leads to the difference on the priming volume. Both proposed device and predicate device comply the ISO 594-2 and ISO 8638 standards. Therefore, we think the differences on the length of main tubes and priming volume will not rain new problems on the safety and effectiveness.

Discussion 6-Biocompatibility

The patient contact components/materials of proposed devices BL11 are covered by the BL 12, and the

patient contact materials of the proposed device BL12 are covered by those of the DORA Tubing Sets for Hemodialysis, as cleared in K161582, which is also manufactured by Bain Medical Equipment(Guangzhou) Co., Ltd. Therefore, this item is considered substantially equivalent.

9. Conclusion

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