June 28, 2024

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

Re: K240164
Trade/Device Name: NovaLine SP-C35 Transducer Protector
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FIB
Dated: May 31, 2024
Received: May 31, 2024

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 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.

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

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)*
K240164

Device Name
NovaLine SP-C35 Transducer Protector

Indications for Use *(Describe)*
The NovaLine SP-C35 Transducer Protector is a single-use, disposable, prescription device intended for use as a protective device for pressure monitors and to help prevent contamination of the fluid pathway in hemodialysis delivery systems.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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: K240164

1. **Date of Preparation:** 05/31/2024

2. **Sponsor Identification**

Bain Medical Equipment (Guangzhou) Co., Ltd.
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3. **Designated Submission Correspondent**

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4. Identification of Proposed Device

Trade Name: NovaLine SP-C35 Transducer Protector
Common Name: Transducer Protector
Models: 956007

Regulatory Information
Regulation Name: Hemodialysis system and accessories
Classification: II
Product Code: FIB
Regulation Number: CFR 876.5820
Review Panel: Gastroenterology/Urology

Indications for Use:

The NovaLine SP-C35 Transducer Protector is a single-use, disposable, prescription device intended for use as a protective device for pressure monitors and to help prevent contamination of the fluid pathway in hemodialysis delivery systems.

Device Description

The NovaLine SP-C35 Transducer Protector consists of a plastic housing that contains a hydrophobic filter with a reference pore size of 0.2 μm. The housing has male and female luer lock connectors that allow its attachment between a blood tubing set and the pressure monitor on a hemodialysis machine.

The NovaLine SP-C35 Transducer Protector is to be used as protective device for pressure monitors as well as to help maintain the sterility of the blood tubing fluid pathway. The 0.2 μm hydrophobic filter helps prevent cross-contamination by viruses, bacterial and particulate matter while preventing the flow of fluids to the hemodialysis machine pressure monitor.

The devices are packaged sterile and labeled for single use only.

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}.

Components	Material	Type of Contact	Contact Duration	Applicable standard
Cap	Polyethylene	Surface device (skin)	<24 hours	ISO 10993
Female luer lock connector	Polyvinylchloride	External communication device (blood path, indirect)	<24 hours	ISO 10993
Male luer lock	Polyvinylchloride	External communication device (blood path, indirect)	<24 hours	ISO 10993

Filter paper	PTFE composite membrane	External communication device (blood path, indirect)	<24 hours	ISO 10993

5. Identification of Predicate Device

Predicate Device
510(k) Number: K072988
Product Name: Nipro Transducer Protector TP-SURE
Manufacturer: NIPRO MEDICAL CORPORATION

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.

Finished Product Performance Test
The proposed devices were tested with appearance, structural integrity, Dimension(ISO 80369-7:2021) and sterility and the test results demonstrated that the proposed device complies with the standards requirements. A side-by-side parallel test with the predicate device demonstrate that the proposed device performs equivalent to the predicate device and is safe and effective when used as intended. A human factors assessment was conducted to demonstrate its safe and effective use.

Product Packaging
Tests were performed on sterilized product packages according to ASTM F88/F88-15 and ASTM F1929-15 to support compliance with pre-established acceptance criteria.

Simulated Distribution Test
Tests were conducted according to ASTM D4169-22 to support compliance with pre-established acceptance criteria.

Shelf life
Packaging performance(Seal Strength and Dye Penetration) and Performance Tests were conducted, including tests per ISO 80369-7. The test resulted demonstrated that the accelerated aged samples complied with the pre-established acceptance criteria.

Bacterial Endotoxin Testing
Endotoxin limit is established as 20 USP Endotoxin Unit (EU) for the proposed device. Test has been conducted by Limulus Amebocyte Lysate (LAL) method according to USP <85> Bacterial Endotoxin Limit.

Biocompatibility Tests
The following tests were conducted to support the biological safety of the proposed device:
cytotoxicity(ISO10993-5), sensitization(ISO 10993-10), irritation(ISO 10993-23), systemic

toxicity(ISO10993-11), pyrogen(ISO10993-11), complement activity (ISO10993-4), partial thromboplastin time(ISO 10993-4), platelet count(ISO 10993-4) and hematology(ISO 10993-4).

Microbial Challenge Testing
Tests were conducted to support the sterile barrier according to ASTM F1671/F1671M-2022, YYT1497-2016 and ASTM F838-2020.

Electrical Safety and EMC
Not applicable.

Software Verification and Validation Testing
Not applicable.

Animal Studies
No animal studies were performed.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Item	Proposed Device	Predicate Device K072988
Model	956007	/
Device Class	II	II
Product Code	FIB	FIB
Regulation Number	21CFR part 876.5820	21CFR part 876.5820
Indications for Use	The NovaLine SP-C35 Transducer Protector is a single-use, disposable, prescription device intended for use as a protective device for pressure monitors and to help prevent contamination of the fluid pathway in hemodialysis delivery systems.	The Nipro Transducer Protector TP-SURE is a single-use, disposable, prescription device intended for use as a protective device for pressure monitors and to help prevent contamination of the fluid pathway in hemodialysis delivery systems.
Feature	Sterile Non-pyrogenic Single Use Prescription Device	Sterile Non-pyrogenic Single Use Prescription Device
Main Configuration	Female Luer Lock Connector	Female Luer Lock Connector
	Filter Paper	Filter Paper
	Male Luer Lock Connector	Male Luer Lock Connector

Item		Proposed Device	Predicate Device K072988
		Cap	Cap
Physical performance	Positive pressure Limitation (mmHg)	500	500
	Negative Pressure Limitation (mmHg)	-500	-500
Performance		Conforms to ISO 80369-7:2016	Conforms to ISO 80369-7:2016
Materials		PVC, PTFE, PET, PE	PP, PTFE, PET
Biocompatibility		Cytotoxicity; Skin Sensitization; Intradermal Reactivity; Acute Systemic Toxicity; Material-mediated Pyrogens; In Vitro Hemolysis; Bacterial endotoxin testing; Complement Activity; Partial Thromboplastin Time; Platelet Count; Hematology	Cytotoxicity; Pyrogenicity Acute Toxicity; Intracutaneous Reactivity; Hemolysis Testing; Implantation Testing; Bacterial Endotoxin Testing
Sterilization		Ebeam, SAL(10^{-6})	EO, SAL(10^{-6})
Labeling		Direction for Use	Direction for Use
		Intended Use	Intended Use
		Description	Description
		Warnings and Cautions	Warnings and Cautions

The proposed device has the similar configuration, indication for use and safety feature as the predicated device. The non-clinical testing demonstrates the product performance of proposed device is similar as that of the predicate device or the product performance of proposed device is acceptable. The biocompatibility of the proposed device comply with ISO 10993 series standards.

9. Substantially Equivalent (SE) Conclusion

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