May 16, 2025

Haolang Medical USA Corporation
c/o Lisa Xu
RA Manager
1100 Bellevue Way NE 8A-533
Bellevue, Washington 98004

Re: K241581
Trade/Device Name: Hemodialysis Catheter
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: Class II
Product Code: MSD
Dated: May 16, 2025
Received: May 16, 2025

Dear Lisa Xu:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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,

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.

Submission Number *(if known)*

k241581

Device Name

Hemodialysis Catheter

Indications for Use *(Describe)*

- The Hemodialysis Catheter is indicated for use in attaining short-term or long-term vascular access for Hemodialysis therapy and apheresis.
* It may be inserted percutaneously and is primarily placed in the internal jugular vein of an patient.
* Alternate insertion sites include subclavian vein as required.
* Catheters greater than 40 cm are intended for femoral vein insertion.
* The curved Hemodialysis Catheter is intended for internal jugular vein insertion.
* 8-10Fr Hemodialysis Catheters can be used in pediatric patients.

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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510(K) Summary-K241581

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: May 20, 2024

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	Haolang Medical USA Corporation
Address:	1100 Bellevue Way NE 8A-533, Bellevue, WA 98004 USA
Contact person:	Lisa Xu
Title:	RA Manager
E-mail:	lisa.xu@haolangmed.com
Tel:	1-425-503-6325

2. Device Identification

Trade/Device Name:	Hemodialysis Catheter
Regulation Number:	21 CFR 876.5540
Regulation Name:	Blood access device and accessories
Regulation Class:	Class II
Product Code:	MSD

3. Predicate Device

Primary Predicate Device#1

510(K) number:	K130851
Device Name:	CASCADE™ Hemodialysis /Apheresis Catheter
Manufacturer:	Health Line International Corporation
Regulation Number:	21 CFR 876.5540
Regulation Name:	Blood access device and accessories
Regulation Class:	Class II
Product Code:	MSD

Predicate Device#2

510(K) number:	K202150
Device Name:	GlidePath™ 7.5F Long-Term Hemodialysis Catheter
Manufacturer:	Bard Peripheral Vascular, Inc
Regulation Number:	21 CFR 876.5540
Regulation Name:	Blood access device and accessories
Regulation Class:	Class II
Product Code:	MSD

Predicate Device#3

510(k) Number	K203767
Device Name:	Pristine™ Long-Term Hemodialysis Catheter
Manufacturer:	Bard Peripheral Vascular, Inc
Common or usual name:	Catheter, Hemodialysis, Implanted
Regulation Number:	21 CFR 876.5540
Regulation Name:	Blood access device and accessories
Regulation Class:	Class II
Product Code:	MSD

4. Device Description

The Hemodialysis Catheter is indicated for use in attaining vascular access for Hemodialysis and Apheresis therapy.
The catheter tubing is made of radiopaque polyurethane with a dual D cross-sectional design, providing independent arterial and venous lumens. The proximal end of the catheter features two luer connectors. The luer connectors are connected to extension legs. The extension legs are made of silicone material .Each extension leg has a catheter clamp, which is durable and can effectively ensure timely closure of the extension leg.The lumen with the red catheter clamp, which is called arterial lumen, is used for blood outflow; The lumen with the blue catheter clamp , which is called venous lumen, is used for blood return. The arterial and venous lumen priming volumes are printed directly on the ID ring of the clamp.
Catheters range from approximately 13-55 cm long and are offered in straight or curved catheter configurations with cuff for long-term implantation.The Hemodialysis Catheter is packaged in a tray with legally marketed accessories intended for use during catheter placement.
The Hemodialysis Catheter Kit is provided sterile, single use.

5. Indication for use

- The Hemodialysis Catheter is indicated for use in attaining short-term or long-term vascular access for Hemodialysis therapy and apheresis.

* It may be inserted percutaneously and is primarily placed in the internal jugular vein of an patient.

* Alternate insertion sites include subclavian vein as required.

* Catheters greater than 40 cm are intended for femoral vein insertion.

* The curved Hemodialysis Catheter is intended for internal jugular vein insertion.

* 8-10Fr Hemodialysis Catheters can be used in pediatric patients.

6. Comparison to Predicate Device

The subject device has similar technological characteristics as compared to the predicate device(s). Differences, if any, are not critical to the intended use of the subject device and do not raise new questions regarding safety and effectiveness.

Feature	Subject device	Primary Predicate Device#1	Comments
Manufacturer/ K#	Haolang Medical USA Corporation	Health Line International Corporation/ K130851	\

Device Name	Hemodialysis Catheter	CASCADE™Hemodialysis /Apheresis Catheter	\
Regulation Number and name,Product Code	21 CFR 876.5540 Blood access device and accessories Class II MSD	21 CFR 876.5540 Blood access device and accessories Class II MSD	Same
Indications for use	- The Hemodialysis Catheter is indicated for use in attaining short-term or long-term vascular access for Hemodialysis therapy and apheresis. * It may be inserted percutaneously and is primarily placed in the internal jugular vein of an patient. * Alternate insertion sites include subclavian vein as required. * Catheters greater than 40 cm are intended for femoral vein insertion. * The curved Hemodialysis Catheter is intended for internal jugular vein insertion. * 8-10Fr Hemodialysis Catheters can be used in pediatric patients.	The CASCADE™ Hemodialysis/Apheresis Catheter is indicated for use in attaining Long-Term (greater than 30 days) vascular access for Hemodialysis therepy and Apheresis. It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient. Alternate insertion sites include subclavian vein as required. The curved CASCADE™ Hemodialysis/Apheresis Catheter is intended for internal jugular vein insertion.	The indications for use of the two devices are basically the same, but 8-10Fr Hemodialysis Catheters of the subject device can be used in pediatric patients. The comparison performance test results with the pediatric catheter （K202150） and the toxicological risk assessment based on the weight of the children proved that the difference does not affect the safety and effectiveness of the device.
Insertion Sites	Internal jugular vein, subclavian vein and femoral vein	Internal jugular vein, subclavian vein and femoral vein	Same
Duration of use	Short-term or Long-Term (greater than 30 days)	Long-Term (greater than 30 days)	SE
Catheter length	13cm~55cm	13~55cm	Same
Catheter O.D.	8F~15.5F	12.5Fr	Different.(01)

Lumen	2	2	Same
Luer connectors	Conforms to ISO 80369-7:2021	Conforms to ISO 80369-7:2021	Same
Catheter configuration	Straight catheter tubing with Straight extension legs , Straight catheter tubing with Curved extension legs , Curved catheter tubing with Straight extension legs	Straight or curved catheter	SE
Patient-Contacting Materials	PU and Silicone	Silicone	Different.(02)
Components	Yes,provided for catheter insertion	Yes,provided for catheter insertion	SE
Sterilization	EO sterile for single use	EO sterile for single use	Same
Shelf life	3 years	3 years	Same

Discussions on the differences from the predicated device:

01 : According to different vessel size of patients, we provided larger catheter size range , but our size range does not exceed that of the hemodialysis catheters already available in the market. For example, GlidePath™ 7.5F Long-Term Hemodialysis Catheter is cleared for marketing under K202150 and 15.5F Pristine™ Long-Term Hemodialysis Catheter is cleared for marketing under K203767.

We had also performed the performance test according to the ISO 10555-1 and the FDA Guidance “Implanted Blood Access Devices for Hemodialysis”. The performance data demonstrates that the difference does not affect the safety and effectiveness of the device.

02: We conducted the biocompatibility evaluation on subject device and determined the endpoint according to ISO 10993-1, which proved that the material of subject device is biocompatibility, the difference of material does not affect the safety and effectiveness of the device.

7. Performance Data

Clinical test:

Clinical testing is not required.

Non-clinical data

Performance:

According to the requirements of FDA guidance “ Implanted Blood Access Devices for Hemodialysis, issued on January 21, 2016 ” and ISO 10555-1:2013 , we performed the following testing:

- Visual assessment

- Air and Liquid Leakage Testing
- Catheter Tensile Testing
- Repeated Clamping
- Priming Volumes
- Luer Connector
- Pressure Versus Flow Rates
- Recirculation Rate
- Mechanical Hemolysis Testing
- Chemical Tolerance Testing
- Particulate Contamination Testing
- Dimension Testing

Shelf Life:
Accelerated aging tests were conducted to confirm the validity of the 3 years shelf life.

Biocompatibility:

The compatibility of the patient-contacting materials in the finished product meets the requirement of Biocompatibility. The Biological Evaluation and Tests are in compliance with the standards of ISO 10993-1, "Biological Evaluation of Medical Devices Part 1:Evaluation and testing within a risk management process".

Sterilization:

- ISO 11607-1:2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.
- ISO 11135: 2014 Sterilization of health care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices

9. Conclusion

Based on the results of above testing, the subject device is substantially equivalent to the predicate device(s) .