July 7, 2021

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

Re: K201726
Trade/Device Name: Arterial Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 1, 2020
Received: September 18, 2020

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 (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,

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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)*
K201726

Device Name
Arterial Catheter

Indications for Use *(Describe)*
The Arterial Catheter permits access to the peripheral arterial circulation.

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

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: June 1, 2021

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:	Arterial Catheter
Models:	18Ga, 20Ga, 21Ga, 22Ga, 24Ga
Regulation Number:	21 CFR 870.1250
Common Name:	Percutaneous Arterial Catheter
Regulation Class:	Class II
Product Code:	DQY

3. Predicate Device

510(K) number:	K171146
Device Name:	Arrow Seldinger Arterial Catheterization Device
Manufacturer:	Arrow International, Inc.
Regulation Number:	21 CFR 870.1250
Regulation Name:	Percutaneous Catheter
Regulation Class:	Class II
Product Code:	DQY

4. Device Description

The Arterial Catheter is a lumen peripherally inserted catheter assembly designed to perform short term access to the peripheral arterial circulatory system for less than 7 days, it is also intended to be used for pressure monitoring. It consists of an introducer needle or catheter-over-needle assembly, spring guide wire, and a catheter assembly that incorporates an extension tubing segment with a slide clamp and a flex tube end cap. These components are used together for catheter insertion using the "Seldinger" catheter-over-guide-wire insertion technique, which divided into three types according to structure: Standard Seedinger; Modified Seedinger-Integrated; Modified Seedinger-Sleeve.

The Arterial Catheter is available in 18 ga, 20 ga, 21 ga, 22 ga and 24 ga, the corresponding diameter of guide wire is 0.025", 0.018", 0.018", 0.015", 0.012". Configurations with usable lengths of

2.5 cm to 23 cm. The catheters are attached to an injection molded polyurethane hub with Luer lock fittings for access attachment.
The Arterial Catheter is provided sterile.

5. Indication for use

The Arterial Catheter permits access to the peripheral arterial circulation.

6. Comparison to Predicate Device

Compared to the predicate devices, the subject device has same intended use, similar product design, performance effectiveness as the predicate device as summarized in the following table.

Feature	Subject device	Predicate device	Comments
Manufacturer/ K#	Haolang Medical USA Corporation	Arrow International, Inc. K171146	--
Trade name and model	Arterial Catheter	Arrow Seldinger Arterial Catheterization Device	--
Classifications name and Regulation Name	21 CFR 870.1250 Percutaneous Catheter Class II DQY	21 CFR 870.1250 Percutaneous Catheter Class II DQY	Same
Indications for use	The Arterial Catheter permits access to the peripheral arterial circulation.	The Arrow Seldinger Arterial Catheterization Devices permit access to the peripheral arterial circulation or to other small vessels	Same
Catheter Gauge Sizes	18 ga, 20 ga, 21 ga, 22 ga and 24 ga	18 ga, 20 ga, 22 ga and 24 ga	We have one more size than predicate device, but we have performed the performance test, the difference does not raise the new risk.
Catheter Usable Length	2.5 cm to 23 cm	5cm – 23cm	According to different usage requirements, our catheter length range is larger, but we have also performed the performance test on which is smaller than the range of predicate device, the difference does not raise the new risk.
Introducer needle size	18Ga, 20Ga, 21Ga, 22Ga,23Ga, 24Ga, 26Ga	18 ga.: 18 ga X 5cm-7cm (2”- 2 ¾”) 20 ga.: 20 ga. X 4cm-	Different, The coverage of the Introducer needle

		7cm (1 ½”- 2 ¾”) 22 ga.: 22 ga. X 4cm (1 ½”)	size is more than that of the predicate device. We used a thinner needle and undergoing the performance test according to the ISO 10555-1 and ISO 11070. The difference does not affect the safety and performance of the device.
Spring Wire Guide Size	0.012”, 0.015”, 0.015”, 0.018”, 0.021”, 0.025”	18 ga.: 0.64mm diameter X 33.5cm-60cm (13”-23”) 20 ga.: 0.533mm diameter X 35cm-50cm (13 ¾”-20”) 22 ga.: 0.533mm diameter X 35cm (13 ¾”) 24 ga.: 0.46mm diameter X 25cm (9 ¾”)	Different, The size coverage of spring Wire Guide Size is more than that of the predicate device. We undergoing the performance test according to the ISO 10555-1 and ISO 11070. The difference does not affect the safety and performance of the device.
Spring Wire Guide Tip	Straight	Straight and J-tip	Same
Spring Wire Guide Depth Markings	Yes	Yes, etched on straight spring wire guides. Not on J-tip spring wire guides	Same
Introducer Method	Introducer needle and introducer catheter-over-needle	Introducer needle and introducer catheter-over-needle	Same
Sterilization Method	EO	EO	Same
Shelf life	3 years	2 years	Different, we have conducted the shelf life validation based on the 3 years, the performance is acceptable, the difference does not affect the safety and performance of the device.
Packaging	PET/LDPE film mated with Tyvek	PET/LDPE film mated with Tyvek	Same

Material	1. Introducer Needle: SUS 304 2. Tubing, Catheter Hub and Luer: PU 3. Needle Hub: ABS 4. Spring guide wire: Niti& Stainless Steel 5. Flex tube: PVC 6. Guide wire slide: HDPE 7. Catheter protector tube: LDPE	1. Introducer Needle: SUS 304 2. Tubing, Catheter Hub and Luer: Polyether urethane 3. Needle Hub: ABS 4. Spring guide wire: SUS 304 5. Flex tube: Not specified 6. Guide wire slide: Not specified 7. Catheter protector tube: Not specified	Different, The introducer needle and the catheter body are made of the same material, but the production process and chemical characterization information of the material is unknown, so it is impossible to prove that its biocompatibility is equivalent. We conducted the biocompatibility evaluation on subject device and determined the endpoint according to ISO 10993-1, which prove that the material of subject device is biocompatibility, the difference of material does not affect the safety and performance of the device.

7. Performance Data

Clinical test:

Clinical testing is not required.

Non-clinical data

Arterial Catheter comply with:

Performance:

According to the requirements of FDA guidance<Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters – Premarket Notification (510(k)) Submissions> ISO 10555-1:2013 we performed the following testing:

- Visual assessment
- Corrosion Resistance
- Liquid Leakage Testing
- Air Leakage Testing
- Flow Rate Testing Report
- Catheter Tensile Testing
- Guidewire Tensile Testing

- Dimensional verification
- Simulated use and Simulated Blood Withdrawal
- Kink Testing
- Torque Strength Testing
- Radiopacity Testing
- Needle testing: Visual assessment; Tensile strength testing of needle and hub; Penetration force

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

Biocompatibility:

The compatibility of the skin-contact component material in the finished product meets the requirement of Biocompatibility. The Biological Evaluation Tests are in compliance with the standards of ISO 10993-1, “Biological Evaluation of Medical Devices”.

Sterilization:

- ISO 11607-1:2016 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 Arterial Catheter is substantially equivalent to the predicate device Arrow Seldinger Arterial Catheterization Device (K171146).