March 5, 2026

Zhuhai DR Medical Instruments Co., Ltd.
Guanglong Zhang
Registration Supervisor
No. 352, Dingwansan Road, Jinwan District
Zhuhai, 519040
China

Re: K251788
Trade/Device Name: Extension tube
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: January 30, 2026
Received: February 2, 2026

Dear Guanglong Zhang:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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,

Shruti N. Mistry -S

Shruti Mistry
Assistant Director
DHT3C: Division of Drug Delivery and General Hospital Devices, and Human Factors
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)*
K251788

Device Name
Extension tube

Indications for Use *(Describe)*
The Extension tube is intended as a connecting line for injection of a contrast and saline during coronary angiography procedures.

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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K251788- 510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of the guidance The 510(k) Program and 21 CFR 880.5860.

510(k) Number: K251788

1. **Date of Preparation:** March 5, 2026

2. **Submitter**

Zhuhai DR Medical Instruments Co., Ltd.
No. 352, Dingwansan Road, Jinwan District, 519040 Zhuhai,
PEOPLE'S REPUBLIC OF CHINA
Contact Person: Mr. Guanglong ZHANG
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3. **Proposed Device**

510(k) submission Number: K251788
Trade Name: Extension tube
Common name: Angiographic injector and syringe
Device Classification Name: Angiographic Injector And Syringe
Review Panel: Cardiovascular
Regulation Number: 21 CFR 870.1650
Regulation Class: Class II
Product Code: DXT
Manufacturer: Zhuhai DR Medical Instruments Co., Ltd.

4. **Predicate device**

510(k) Number: K244038
Product Name: High Pressure Tubing
Review Panel: Cardiovascular
Regulation Number: 21 CFR 870.1650
Device Classification name: Angiographic Injector And Syringe
Regulation Class: Class II
Product Code: DXT
Manufacturer: Shandong INT Medical Instruments Co., Ltd.

5. Indications for Use

The Extension tube is intended as a connecting line for injection of a contrast and saline during coronary angiography procedures.

6. Device description

The Extension tube is made up of connectors, male and/or female luer, caps and tubing, with the maximum injection pressure of 1200psi, as a connecting line for direct injection of contrast media or saline. It is single use and supplied sterile by Ethylene Oxide.

7. Comparison to the Predicate Device

Extension tube is substantially equivalent in indication for use, design, sterilization method to the predicate devices, High Pressure Tubing, K244038. The differences in components between the devices do not raise different questions of safety and effectiveness.

Item	Proposed Device K251788	Predicate Device K244038	Remark
Manufacturer	Zhuhai DR Medical Instruments Co., Ltd.	Shandong INT Medical Instruments Co., Ltd	/
Product code	DXT	DXT	Same
Device Classification	Class II, 21 CFR 870.1650 Angiographic Injector And Syringe	Class II, 21 CFR 870.1650 Angiographic Injector And Syringe	Same
Indications for Use	The Extension tube is intended as a connecting line for injection of a contrast and saline during coronary angiography procedures.	High Pressure Tubing is indicated for use in PTCA surgery to connect the angiographic catheter and the angiographic syringe to deliver contrast media.	Same
Principle of Operation	1.According to needed function, select suitable type. 2.Take out Extension tube from sterile package, remove screw cover and protective cap at both ends of Extension tube. 3.Through male and female luer connector coordinate so as to assemble High pressure tube to corresponding infusion instruments. 4.Turn on the mains switch.	1.Using aseptic technique, remove the protective caps from both ends of High Pressure Tubing. 2.Securely attach female luer of High Pressure Tubing to the mechanical injector syringe. 3.Prepare High Pressure Tubing for use by filling with contrast media, carefully removing any air bubbles from the fluid column. 4.Securely attach male luer of High Pressure Tubing to the catheter hub, using a ‘wet to wet’ connection, carefully avoiding air bubbles during the connection, Slowly pull a small negative vacuum on the mechanical injector; gently tap on the connection points and the syringe to draw any small bubbles or particulate into the top of the syringe barrel. 5.Make sure tip of mechanical injector syringe is pointing down toward the table. Program injector and dispense contrast media per physician’s orders.	Same. The operating principles and methods are essentially consistent, with the Predicate Device description being more detailed. The underlying operational principles remain the same.

Models	SKU 72233-01(23cm), SKU 72233-02(150cm), SKU 72233-03(150cm), SKU 72233-04(250cm), SKU 72233-05(150cm), SKU 72233-06(150cm), , SKU 72233-07(150cm), SKU 72233-08(120cm), SKU 72233-09(120cm), SKU 72233-10(273cm), SKU 72233-11(275cm), SKU 72233-12(31cm), SKU 72233-09A(180cm), SKU 72233-21(224cm), SKU 72233-22(404cm), All models length range in 23 cm ~ 404 cm. Inner diameter:1.5, 1.8, 2.1, 2.2 and 2.5 mm; Outer diameter:3.6 mm.	10cm~350cm; Inner diameter:1.8 mm; Outer diameter:3.6 mm.	Different, Comment 1
Main Configuration/Components	Male/Female luer connector，Y-type needle access adapter，Rotary connector，tube，Beveled trocar assembly	Tubing, Male/female luer connector, Rotating male luer connector, protective caps.	Different, Comment 2
Use	Single use	Single use	Same
Pressure Rating	65 psi ~1200 psi	1200 psi	same
Conical Fitting	Comply with ISO 80369-7	Comply with ISO 80369-7	same
Biocompatibility	ISO 10993 series	ISO 10993 series	Same
Shelf-life	5 years	3 years	Different, Comment 3
Sterilization method	EO sterilization	EO sterilization	Same
Sterility assurance level	10^{-6}	10^{-6}	Same

Comparison Discussion

The following comments was the differences between the subject and predicate device:

Comment 1 - Models

The length ranges of some models of the subject device are longer than those of the predicate devices, and some of their inner diameters are smaller. The subject device has undergone the flow rate verification in Bench performance testing which was pursuant to ISO 10555-1:2023 and met the requirement. So the difference in its length and inner meter do not introduce new risks and do not affect the device's safety or effectiveness.

Comment 2 - Main Configuration/Components

The subject device and predicate device have similar components, such as male/female luer connector, tubing and valve. The subject device has different components from the predicate device. The subject device has undergone the examination which was pursuant to ISO 8536-4:2019, ISO 8536-9:2015, ISO 8536-10:2015, ISO 8536-12:2021, ISO 80369-7:2021, AAMI ANSI CN27:2021 and met the requirements. The differences of configurations between the subject device and predicate device do not raise different questions of safety and effectiveness.

Comment 3 - Shelf-life

The subject device has the longer shelf-life. According to the Package Integrity Test Report which was was accessed in accordance with ASTM F1929, ASTM F1886 and ASTM F88 after conducting an accelerated aging test and simulated shipping testing. The results of the accelerated aging study have not shown any significant changes in product characteristics and Packaging integrity.

8. Bench Performance Testing

All necessary bench and non-clinical testing was conducted on Extension tube to support a determination of substantial equivalence to the predicate devices. The non-clinical, bench testing included:

Items	Standards	Conclusion
1. Appearance	ISO 8536-9:2015	Pass
2. Length	/	Pass
3. Luer connector	ISO 80369-7:2021	Pass
4. Leakage	ISO 8536-9:2015	Pass
5. Tensile strength	ISO 8536-9:2015	Pass
6. Protective caps	ISO 8536-4:2019	Pass
7. Check valve - Counterflow pressure resistance	ISO 8536-12:2021	Pass
8. Flow rate	ISO 10555-1:2023	Pass
9. Check valve - Blocking performance	ISO 8536-12:2021	Pass
10. Check valve - Opening pressure	ISO 8536-12:2021	Pass
11. Particulate contamination	USP<788>method 1	Pass
12. Reducing (oxidizable) matter	ISO 8536-4:2019	Pass
13. Metal ions	ISO 8536-4:2019	Pass
14. Titration acidity or alkalinity	ISO 8536-4:2019	Pass
15. Residue on evaporation	ISO 8536-4:2019	Pass
16. UV absorption of extract solution	ISO 8536-4:2019	Pass
17. Residual ethylene oxide	ISO 10993-7:2008	Pass

9. Biocompatibility Testing

Biocompatibility testing was conducted in compliance with ISO 10993-1, for externally communicating devices with limited exposure (<24 hours) to blood path, indirect, and included below test items.

Items	Standards	Conclusion
Cytotoxicity	ISO 10993-5:2009	Pass
Sensitization	ISO 10993-10:2021	Pass
Irritation or intracutaneous reactivity	ISO 10993-23:2021	Pass
Acute Systemic Toxicity	ISO 10993-11:2017	Pass
Material-mediated pyrogenicity	ISO 10993-11:2017	Pass
Hemocompatibility -- Hemolysis testing	ASTM F756-17/ ISO10993-4 : 2017	Pass

The subject device, Extension tube is subject to biocompatibility test in accordance with ISO 10993-1, the test result demonstrate that Extension tube is safe.

10. Sterilization

The subject device is sterilized by traditional Ethylene Oxide sterilization methods. The Ethylene Oxide sterilization process is validated as per 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, Overkill Method: This method is based on demonstrating that the sterilization of a microbial challenge (biological indicator) exceeds the challenge posed by the bioburden of the product. Confirmatory EO residual testing was conducted on the subject device to confirm that the design differences did not impact residual EO levels of the device. The testing confirmed that EO residuals were within the limits specified in ISO 10993-7.

11. Packaging and Shelf Life

The subject device is supplied sterile. The sterile barrier packaging is designed to maintain sterility throughout the labeled shelf life 5 years.
The shelf-life study was planned as per ASTM F1980 recommended conditions. The study was conducted with elevated temperature conditions and with real time conditions. The packaging system was accessed in accordance with ASTM F1929, ASTM F1886 and ASTM F88 after conducting an accelerated aging test and simulated shipping testing. The results of the accelerated aging study have not shown any significant changes in product characteristics and Packaging integrity.

12. Clinical Testing

No clinical study is included in this submission.

13. Conclusion

The proposed device has the same indications and has similar design features and technological characteristics as the predicate device, High Pressure Tubing, K244038. Non-clinical testing data demonstrates that the proposed device is substantially equivalent to the predicate device.