December 23, 2024

Shandong INT Medical Instruments Co., Ltd.
Zhang Wei
RA specialist
No. 188, Fuzhou Road
Rizhao, Shandong 276599
China

Re: K242143
Trade/Device Name: Angiography Injector
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: December 5, 2024
Received: December 6, 2024

Dear Zhang Wei:

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.

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242143

Device Name

Angiography Injector

Indications for Use *(Describe)*

The Angiography Injector is intended to aspirate and inject contrast media in the interventional procedure. It can also be used to inject fluids into, or withdraw fluids from the body.

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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K242143 - 510(K) summary

I. Submitter

Submission Sponsor	Shandong INT Medical Instruments Co., Ltd. No. 188, Fuzhou Road, Rizhao, Shandong 276599, China
Submission Correspondent:	Zhang Wei RA specialist Tel.: +8615601952252 E-mail: zhangwei@int-medical.com
Submission Date:	December 5, 2024

II. Proposed Device

Trade or Proprietary Name:	Angiography Injector
Common or Usual Name:	Angiographic Injector And Syringe
Regulation Number:	21 CFR 870.1650
Product code:	DXT
Regulatory Class:	Class II
Review Panel:	Cardiovascular
Reason for Submission:	New device

III. Predicate Devices

Primary predicate device	
510(k) Number:	K163084
Trade name:	Merit Coronary Control Syringe
Classification:	Class II
Product Code:	DXT
Manufacturer:	Merit Medical Systems, Inc.

IV. Indications for Use

The Angiography Injector is intended to aspirate and inject contrast media in the interventional procedure. It can also be used to inject fluids into, or withdraw fluids from the body.

V. Device Description

The Angiography Injector is intended to provide the function of aspirating and injecting contrast media in the interventional procedure. It can also be used to inject fluids into, or withdraw fluids from the body. The proposed device is intended for single use and is provided sterile using EO sterilization.

The Angiography Injector consists of six components: 1) Piston, 2) Plunger cap, 3) Push-button 4) Barrel, 5) Plunger and 6) Adapter (rotating or fixed). The proposed device is available in volume of 6mL, 8mL, 10mL and 12mL.

The primary package is blister package and plastic paper package. The blister package and plastic paper package all consist of PE film and Tyvek®2FS paper.

VI. Comparison to the Predicate Device

The proposed Angiography Injector has the same indications for use, as well as similar materials, design and mode of action as the Merit Coronary Control Syringe predicate device.

Item	Proposed device	Predicate device K163084	Discussion
Product name	Angiography Injector	Merit Coronary Control Syringe	-
Product Code	DXT	DXT	Same
Regulation No.	21 CFR 870.1650	21 CFR 870.1650	Same
Class	Class II	Class II	Same
Indications for Use	The Angiography Injector is intended to aspirate and inject contrast media in the interventional procedure. It can also be used to inject fluids into, or withdraw fluids from the body.	The Merit Coronary Control Syringe is intended to be used for the intraarterial or intravenous administration of radiographic contrast media. The syringe can also be used to inject fluids into, or withdraw fluids from the body.	Same
Mode of Action	Intended for manual use	Intended for manual use	Same
Environment of use	Surgical operating room	Surgical operating room	Same
Materials	Barrel - PC Plunger - ABS Piston - Polyisoprene rubber Plunger Cap - HDPE Push-button - ABS Rotating adapter - PC + Silicone	Barrel - PC Plunger - ABS Seal - Silicone Rotator O - Ring - Silicone	Similar[1] (Discussion 1)
Design Standards	Luer Connector to ISO 80369-7 Injector to ISO 7886-1	Luer Connector to ISO 80369-7 Injector to ISO 7886-1	Same
Duration of Use	Less than 24h	Less than 24h	Same
Volume	6 ~12mL	6~20 mL	Similar[2] (Discussion 2)
Graduation	Printed with accurate graduation lines	Printed with accurate graduation lines	Same

	that are compliant with ISO 7886-1.	that are compliant with ISO 7886-1.	
Sterile	Yes	Yes	Same
Single for Use	Yes	Yes	Same
Prescription (Rx Only)	Yes	Yes	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
SAL	10^{-6}	10^{-6}	Same
Shelf life	3 years	3 years	Same
Barrel Transparency	Clear	Clear	Same
Physical and Mechanical	ISO 7886-1	ISO 7886-1	Same

Comparison Discussion

The following differences between the subject and predicate device do not raise new or different questions of safety and effectiveness.

Discussion 1[1] The difference in the materials does not raise additional questions for safety and effectiveness of the device when compared to the predicate device. The biocompatibility evaluation test of the subject devices have been performed on the final finished device which includes all materials of construction. The test results show that the acceptance criteria have been met.

Discussion 2[2] The volume of the proposed device is slightly different from the predicate device. This difference does not raise new or different questions of safety and effectiveness when compared to the predicate device. The performance tests have been carried out according to ISO 7886, and the test results show that the requirements of the standard have been met.

VII. Bench Performance Testing

The completion of the performance testing listed in the table below demonstrates that the proposed device meets the defined design specifications and is suitable for its intended use.

Test Items:

Appearance

Lubricant

Graduated scale

Luer connector

Nozzle lumen

Force to operate the piston

Freedom from air and liquid leakage past plunger stopper

Tolerance on graduated capacity

Fit of plunger stopper/plunger in barrel

Dead space

Particulate Evaluation

Simulated use testing

Reducing (oxidizable) matter

Limits for extractable metals

Limits for acidity or alkalinity

Residue of evaporation

UV adsorption

EO residual

Sterility

Bacterial endotoxin

VIII. Biocompatibility Testing

To demonstrate the biological safety of the body-contacting materials of the Angiography Injector，the following biocompatibility testing in accordance with "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"; Guidance for Industry and Food and Drug Administration Staff" were completed.

Test Items:

In Vitro Cytotoxicity Test

In Vitro Hemolytic

Intracutaneous Reactivity

Skin Sensitization

Acute Systemic Toxicity

Pyrogen

IX. Sterilization

The subject device is sterilized by traditional Ethylene Oxide sterilization methods. The Ethylene Oxide sterilization process is validated as per ISO 11135-1 Sterilization of health care products – Ethylene Oxide - Part 1 (Requirements for development, validation and routine control of a sterilization process for medical devices), Method C (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.

X. Packaging and Shelf Life

The subject device is supplied sterile. The sterile barrier packaging is designed to maintain sterility until it open.

The proposed shelf life of subject device is 3 years. The shelf life study for Angiography Injector was planned as per ASTM 1980 recommended conditions. The study was conducted with elevated temperature conditions and with real time conditions. As per ASTM 1980 recommended accelerated aging conditions were used to establish the shelf life of the Angiography Injector. The real time shelf time study is still on going. The results of the accelerated aging study has not shown any significant changes in product characteristics.

XI. Clinical Testing

No clinical study is included in this submission.

XII. Conclusion

The proposed device has the same indications and has similar design features and technological characteristic as the predicate device. Non-clinical testing data demonstrates that the proposed device is substantially equivalent to the predicate device.