April 16, 2026

Shenzhen Maiwei Biotech Co., Ltd.
% Jie Yang, Consultant
Chonconn Consulting Co., Ltd.
Room 504, Block C, No. 1029 Nanhai Avenue,
Nanshan District
Shenzhen, Guangdong 518067, China

Re: K253048
Trade/Device Name: High Pressure Syringe; Pressure Connecting Tube; Spike; Transfer Tube; Quick Fill Tube
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: March 19, 2026
Received: March 19, 2026

Dear Jie Yang:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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
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Office of Product Evaluation and Quality
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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)*
K253048

Device Name
High Pressure Syringe; Pressure Connecting Tube; Spike; Transfer Tube; Quick fill tube

Indications for Use *(Describe)*
The high pressure syringe, pressure connecting tube, quick fill tube, spike and transfer tube are intended to connect with US legally marketed angiographic injectors for the injection of Contrast media or saline. They are for single use and provided sterile.
For a complete list of compatible device models, accessories, and compatible injectors, refer to the device Instructions for Use.

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

K253048

Prepared Date: 2026/04/16

1. Submission sponsor

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3. Subject Device Information

Trade/Device Name	High Pressure Syringe ; Pressure Connecting Tube; Spike; Transfer tube; Quick fill tube
Common Name	Angiographic injector and syringe
Classification Name	Injector And Syringe, Angiographic
Regulation Number	870.1650
Product code	DXT

4. Predicate Device

Predicate #:K211564
Trade name: Sterile High-pressure Angiographic Syringes for single-use
Product code: DXT

5. Device Description

The subject devices, including high pressure syringe, pressure connecting tube, quick fill tube, spike and transfer tube, are available in different configuration and models. All devices are for single use and provided sterile.

High pressure syringe: The syringes are compatible with various US legally marketed angiographic injectors, as listed in Table 1: Compatibility Between Syringes and Injectors. An accessory prime tube is specified for use with syringes A03103 and A03106.

Pressure connecting tube: Pressure connecting tubes, used to connect the syringe to the catheter, are available in multiple configurations: straight tube, coil tube, Type Y, and Type T. Their pressure specifications are detailed in Table 2: Pressure Connecting Tube Specifications.

Spike: Spikes are used to draw contrast media/saline into the syringe barrel before the syringe is installed. Pressure specifications for spikes are provided in Table 3: Pressure Specifications for Spikes.

Transfer tube: A transfer tube combines a pressure connecting tube and a spike, connected via a T-valve. It facilitates drawing contrast media/saline into the syringe barrel (using the spike end) and connecting the syringe to the catheter (via the other two ends). Pressure specifications are listed in Table 4: Pressure Specifications for Transfer Tubes.

Quick Fill Tube: Quick fill tubes serve the same purpose as spikes for pre-installation media/saline drawing. Their pressure specifications are outlined in Table 5: Specifications for Quick Fill Tubes.

Table 1 Compatibility between Syringe and Injectors

Model	Volume (ml)	Pressure Limit	Injector
A01101	200	350psi	VCT610, K991557 ECT710, K934086
A03103	200	350psi	Stellant-S, K182273
A03106	200/200	350psi	Stellant-D, K182273
A02203	150	1200psi	Mark V, K822536
A03201	200	1200psi	
A05203	200	1200psi	Mark VII, K112086
A01305	65/65	350psi	Spectris, K935668
A02305	65/115	350psi	Spectris, K935668
B03203	150	1200psi	Angiomat Illumena,K963071
B02203	150	1200psi	Angiomat 6000, K944875
B04106	200/200	350psi	OptiVantage Dual, K063503

Model	Volume (ml)	Pressure Limit	Injector
B01103	200	350psi	CT OptiOne, K152361 CT9000 & CT9000ADV, K912944
B06106	125/125	350psi	CT OptiOne, K152361
B06103	125	350psi	CT OptiOne, K152361
B01305	60/60	350psi	OPTISTAR, K073592
B01301	60	350psi	OPTISTAR MR, K984088
C06106	200/200	350psi	Dual Shot,Dual K052633
C07106	100/100	350psi	Dual Shot,Dual K052633
C02203	125	1200psi	120S K092896
C03203	150	1200psi	Rempress, K092896
C01305	60/60	350psi	Sonic Shot K091734
F02106	200/200	350psi	Empower CT K071378
F02103	200	350psi	EmpowerCT and Empower CTA Injector Systems K063029
F01305	100/100	350psi	Empower MRI K062449

Table 2 Pressure Connecting Tube Specifications

Model	Length	Pressure limit	Type
S0L062	320cm	350psi	Straight
S0L150	250cm	350psi	Coil
D0L100	320cm	350psi	Y, Straight
D0L100C	320cm	350psi	Y, Coil
D0L100T	320cm	350psi	T, Straight
D0L100TC	320cm	350psi	T, Coil
S0H150	150cm	1200psi	Straight
S0H250	250cm	1200psi	Straight

Table 3 Pressure Specifications for Spike

Model	Length	Pressure limit	Type
S0L000	43.2mm	/	Small spike
S0L003	52.3mm	/	Large spike
S1L020	120cm	350psi	Transfer set
S1L031	150cm	350psi	Transfer set with one inline drip chamber
S1L032	150cm	350psi	Transfer set with Clip

Table 4 Pressure Specifications for Transfer Tube

Model	Length	Pressure limit	Type
D1L006	150cm	350psi	Transfer Tube with two inline drip chambers
D1L151	150cm	350psi	Transfer Tube

Table 5 Specifications for Quick Fill Tube

Model	Length
S0L001	240mm

6. Intended use & Indication for use

The high pressure syringe, pressure connecting tube, quick fill tube, spike and transfer tube are intended to connect with US legally marketed angiographic injectors for the injection of Contrast media or saline.

They are for single use and provided sterile.

For a complete list of compatible device models, accessories, and compatible injectors, refer to the device Instructions for Use.

7. Comparison to the Predicate Device

Characteristic	Subject device K253048	Primary Predicate device K211564	Remarks
Device name	high pressure syringe	Syringe	Same
	pressure connecting tube	Connection Tube	Same
	quick fill tube spike transfer tube	J shape tube Spike	Different. Note 1.
Product Code	DXT	DXT	Same
Regulation Number	21 CFR 870.1650	21 CFR 870.1650	Same
Indications for use	The high pressure syringe, pressure connecting tube, quick fill tube, spike and transfer tube are intended to connect with US legally marketed	Sterile High-pressure Angiographic Syringes for Single-use are intended for the injection of Contrast media or saline; they shall be used with US legally	Different, Note 2

		angiographic injectors for the injection of Contrast media or saline. They are for single use and provided sterile. For a complete list of compatible device models, accessories, and compatible injectors, refer to the device Instructions for Use.	marketed angiographic injectors	
Mode of operation		Power-driven operation, single use	Power-driven operation, single use	Same
Sterility		EO Sterilized	EO Sterilized	Same
Single Use		Yes	Yes	Same
Accessory		Prime tube	N/A	Different, note 3
Maximum withstanding pressure	**Syringe**	350psi, 1200psi	300psi, 400psi, 1200psi	Different, note 4
	Pressure Connecting tube	350psi, 1200psi	300psi, 400psi, 1200psi	Different, note 4
	Quick fill tube/ J shape tube	NA	NA	Same
	Spike(including transfer tube)	350psi	400psi	Different , note 4
Dimensions	**Syringe (Volume, ml)**	60, 125, 150, 200, 200/200, 100/100, 65/65,125/125 65/115, 60/60	200, 150, 125, 130, 100, 200/200, 100/100, 65/65, 65/115, 60/60, 50/50	Different, note 5
	Pressure connecting Tube (length, mm)	1500~3200, 1500,2500, 3200	200~2500, 1500~2500, 1500, 1800, 2000, 2500, 500, 750, 1000, 1200	Different, note 5
	Quick fill tube/ J	240	240	Same

	shape tube (length, mm)			
	Spike and Transfer Tube (length, mm)	43.2, 52.3, 1200,1500	58.8, 47.3, 1000, 2800, 1200, 2900, 180, 260, 340, 420, 500, 450, 550, 600	Different, note 5
Performance				
Syringe		ISO 7886	ISO 7886	Same
Luer connector		ISO 80369-7	ISO 594-1; ISO 594-2	Different, note 6
Compatibility Testing with Corresponding Injectors", respectively		Pass	Pass	Same
Patient-Contact Material				
Syringe	**Barrel**	PC (Polycarbonate) or PP (Polypropylene)	PP (polypropylene) or PET (Polyethylene terephthalate)	Different, note 7
	Plunger	PE (Polyethylene)	Polyisoprene rubber	Different, note 7
	Lubricant	Polydimethylsiloxane	Polydimethylsiloxane	Same
Pressure connecting tube	**Tubing**	PVC (Polyvinylchloride not made with DEHP)	PVC (Polyvinylchloride) or PVC (Polyvinylchloride not made with DEHP)or PU(Polyurethane)	Different, note 7
	Luer Connectors	PC (Polycarbonate)	PC (Polycarbonate)	Same
	UV adhesive	Ultraviolet adhesive	Ultraviolet adhesive	Same
Spike/Transfer tube	**Closure-piercing device**	ABS (acrylonitrilebutadiene-styrene)	ABS (acrylonitrilebutadiene-styrene)	Same
	Filter membrane	PP (polypropylene)	PP (polypropylene)	Same
	Tube	Polyvinyl chloride (PVC)	Polyvinyl chloride (PVC)	Same
	Luer	Polycarbonate (PC)	Polycarbonate (PC)	Same

	Connector			
	Protective cap	PP (Polypropylene)	ABS (acrylonitrilebutadiene-styrene)	Different, note 7
Quick fill tube/J shape tube	**Tube**	PE (Polyethylene)	PE (Polyethylene)	Same
Biocompatibility		No Cytotoxicity	No Cytotoxicity	Same
		No Irritation	No Irritation	Same
		No Sensitization	No Sensitization	Same
		No Pyrogen	No Pyrogen	Same
		No Acute Toxicity	No Acute Toxicity	Same
		No Hemolysis	No Hemolysis	Same
Endotoxin Limit		20 EU per device	20 EU per device	Same
EO/ECH residue limit		Limited Contact:≤ 24h EO: 0.6mg/ day ECH: 1.28mg /day For 10kg patient (Children) as per ISO 10993-7	Limited Contact:≤ 24h EO: 0.6mg/ day ECH: 1.28mg /day For 10kg patient (Children) as per ISO 10993-7	Same
Population		Not intended for infant or neonatal use	Not intended for infant or neonatal use	Same
Shelf life		5 years	5 years	Same

Note 1:

The transfer tube has same design as the spike of the predicate device. They are substantially equivalent. The quick fill tube corresponds to the J shape tube of the predicate device. The difference of the device name does not raise new questions of safety and effectiveness when compared to the predicate device.

Note 2:

The indications for use are substantially equivalent. The difference in wording reflects a descriptive variation only and does not change the intended use of the devices. The difference does not raise new questions of safety and effectiveness when compared to the predicate device.

Note 3:

The accessory prime tube is specified for use with syringes A03103 and A03106 which is compatible with Stellant-S/ Stellant-D, K182273. The prime tube is composed of polyethylene (PE) tubing and a PET particle filter. It is used only for priming and is removed before patient connection. Biocompatibility evaluation and bench performance testing has been conducted for the priming. Furthermore, it does not affect the safety or performance of the main device during patient use. Therefore, this difference does not raise new questions of safety and effectiveness when compared to the predicate device.

Note 4:

The subject devices offer fewer options for maximum withstanding pressure. Specifically, some subject devices claim a value of 350 psi, which falls between the 300 psi and 400 psi claims of the predicate device. The claimed pressure values have been verified through performance testing, so this difference does not raise new questions of safety and effectiveness when compared to the predicate device.

Note 5:

There are differences in the available volume or length options between the subject devices and the predicate device. However, the available values are similar and within a comparable range. These differences merely provide additional clinical choices rather than new variations. Therefore, the differences do not raise new questions of safety and effectiveness when compared to the predicate device.

Note 6:

The subject devices comply with the latest effective version of the standard for verifying Luer connectors, whereas the predicate device adheres to an older version. Therefore, this difference does not raise new questions of safety and effectiveness when compared to the predicate device.

Note 7:

The subject devices use different materials for certain components compared to the predicate device. Patient-contacting materials have been evaluated through biocompatibility testing in accordance with ISO 10993-1. Therefore, this difference does not raise new questions of safety and effectiveness when compared to the predicate device.

8. Performance Data

The subject device was subjected to the following applicable testing to assure reliable design and performance under the specified testing parameters:

Biocompatibility Testing:

Per ISO 10993-1: 2018 and FDA guidance, the following tests were performed to ensure

the biocompatibility of the subject device.

- Cytotoxicity
- Sensitization
- intracutaneous reactivity
- Material mediated pyrogenicity
- Acute systemic toxicity
- Hemocompatibility

Sterilization and shelf life testing

Sterilization Process has been validated accordance with ISO 11135:2014.
EO/ECH residual test was performed according to ISO 10993-7.
The shelf life is determined by accelerated aging test according to ASTM F1980-21.
Package validation was conducted according to ISO 11607-1:2019.

Mechanical and Bench Testing:

ISO 8536-4 Sixth edition 2019-09 Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed
ISO 80369-7 Second edition 2021-05 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
USP-NF M98830_02_01 <85> Bacterial Endotoxins Test
ISO 7886-1 Second edition 2017-05 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
ISO 7886-2 Second edition 2020-04 Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps
USP <788> Particular Matter in Injections

9. Clinical study

No clinical study is included in this submission

10. Conclusion

Substantial equivalence comparisons, performance testing and compliance with voluntary standards demonstrate that the subject device is substantially equivalent to the predicate device.