October 28, 2020

Youwo (Guangzhou) Medical Device Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K201395
Trade/Device Name: Sterile High-pressure Angiographic Syringes for single-use
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: September 24, 2020
Received: September 25, 2020

Dear Diana Hong:

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 CAPT Alan Stevens
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)*
K201395

Device Name
Sterile High-pressure Angiographic Syringes for Single-use

Indications for Use *(Describe)*
The proposed device is intended for the injection of contrast media or saline. This syringe is for single use with US legally marketed angiographic injectors.

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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Tab 6 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K201395

1. Date of Preparation: 10/20/2020

2. Sponsor Identification

Youwo (Guangzhou) Medical Device Co., Ltd.
First Floor and Fourth Floor, Building D, No.188 Kaiyuan Ave, Hi-tech Industrial Development Zone, 510530 Guangzhou, P.R. China

Establishment Registration Number: Not yet registered

Contact Person: Meijin Song
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Huifan Wang (Alternative Contact Person)

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Fax: +1-360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Sterile High-pressure Angiographic Syringes for Single-use
Common Name: Disposable angiographic syringe

Regulatory Information

Classification Name: Angiographic injector and syringe
Classification: II
Product Code: DXT
Regulation Number: 21 CFR 870.1650
Review Panel: Cardiovascular

Indications for Use Statement:
The proposed device is intended for the injection of contrast media or saline. This syringe is for single use with US legally marketed angiographic injectors.

Device Description

The proposed devices are available in packs, which may include different configurations of syringes and accessories. The syringes are plastic, disposable syringes, which are available in various models and configurations. They are intended to be used with an U.S. legally marketed angiography injector, compatibilities are shown in Table 1.

Table 1 Compatibility between Syringes and Injectors

No	Model	Single or Dual Shots	Injector
1	I-50ml -B	Single	K091734
2	I-60ml -A	Single	K890898
3	I-60ml -B	Single	K984088
4	I-65ml -A	Single	K033247
5	I-100ml -B	Single	K091734
6	I-115ml -A	Single	K033247
7	I-150ml -A	Single	K132928
8	I-190ml -A	Single	K023183
9	I-200ml -A	Single	K023183
10	I-200ml -B	Single	K091734
11	II-125ml -A	Single	K052633
12	II-150ml -A	Single	K903390
13	II-200ml -A	Single	K031339

14	I 200-200ml -A	Dual	K023183
15	I 200-200ml -B	Dual	K091734
16	I 115-115ml -A	Dual	K033247
17	I 100-100ml -B	Dual	K091734
18	I 100-200ml -B	Dual	K091734
19	I 50-100ml -B	Dual	K091734
20	I 50-200ml -B	Dual	K091734
21	I 60-60ml -A	Dual	K890898
22	I 60-60ml -B	Dual	K984088
23	I 65-65ml -A	Dual	K935668
24	I 65-115ml -A	Dual	K033247
25	II 200-200ml -A	Dual	K031339
26	I 190-190ml -A	Dual	K023183
27	I 50-50ml -B	Dual	K091734
28	II 100-100ml -B	Dual	K091734
29	I 60-100ml -B	Dual	K052633

The connection tubes, which is used to connect the syringe and the catheter. The tubes are available in two configurations, which are Type Y and Type T tube. The different between these tubes is tube shape, which is available in Y shape for Y tube and T shape for T tube.

J shape tube, which is used to draw contrast media/ saline into the syringe barrel.

Spikes, which are used to draw contrast media/saline into the syringe barrel.

5. Identification of Predicate Device

510(k) Number: K151960
Product Name: Sterile High-pressure Angiographic Syringes for Single-use
Manufacturer: Shenzhen BaoAn Medical Supplies Co., Ltd.

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-7:2008 Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals;

- ASTM F88/F88M-15 Standard test method for seal strength of flexible barrier materials;
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration;
- USP 41-NF36 2018 <85> Bacterial Endotoxins Limit;
- ISO 11737-2:2009 Sterilization of medical devices- Microbiological methods- Part 2: Test of sterility performed in the definition, validation and maintenance of a sterilization process;
- ISO 7886-2:1996 Sterile hypodermic syringes for single use -- Part 2: Syringes for use with power-driven syringe pumps;
- ISO 594-1:1986 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General Requirements;
- ISO 594-2:1998 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock Fitting;
- ISO 10993-1: 2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity;
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization;
- ISO 10993-11:2017 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity;
- USP <788> Particulate matters
- ASTM F 756-17, Standard practice for assessment of hemolytic properties of material
- USP 41-NF36:2018 <151> Pyrogen Test (USP Rabbit Test)

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 2 General Comparison

ITEM	**Proposed Device**	**Predicate Device K151960**	**Remark**
Product Code	DXT	DXT	Same
Regulation No.	CFR 870.1650	CFR 870.1650	Same
Class	II	II	Same
Intended Use	The proposed device is intended for the injection of contrast media or saline. This syringe is for single use with US legally marketed angiographic injectors.	The proposed device is intended for the injection of contrast media or saline. This syringe is for single use with US legally marketed angiographic injectors.	Same
Mode of Operation	Power-Driven	Power-Driven	Same
Configuration	Angiographic Syringe	Angiographic Syringe	Same
	Connection tube	Connection tube	Same
	J shape tube/ Spike	J shape tube/Spike	Same
Specification			
Syringe volume (ml)	Single shot: 50, 60, 65, 100, 115, 150, 190, 200, 125 Dual shot: 200/200, 115/115, 100/100, 100/200, 50/100, 50/200, 60/60, 65/65, 65/115, 190/190, 50/50, 60/100	Single shot: 200, 150, 130 Dual shot: 200/200, 65/65, 65/115, 60/60, 60/100	Analysis 1
Connection tube length (mm)	300, 500, 600, 750, 900, 1000, 1200, 1500, 1800, 2000, 2500, 3200	1500, 1800, 500, 700, 1000, 1200	
Spike length (mm)	36, 39, 44, 49	58.85, 47.35	
J shape tube length (mm)	250	240	
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Performance	Comply with: ISO 7886-1, ISO 594-1 and ISO 594-2	Comply with: ISO 7886-1, ISO 594-1 and ISO 594-2	Same
Biocompatibility			
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same
Irritation	No Irritation	No Irritation	

Sensitization	No Sensitization	No Sensitization	
Acute Toxicity	No Acute Toxicity	No Acute Toxicity	
Hemolysis	No Hemolysis	No Hemolysis	
Pyrogen	No Pyrogen	No Pyrogen	
Particulate testing	Comply with USP 788	Comply with USP 788	Same
Sterilization	EO Sterilized	EO Sterilized	Same
Patient-contact material- Angiographic syringe			
Barrel	polypropylene (PP) or Polyethylene terephthalate (PET)	polypropylene (PP) or Polyethylene terephthalate (PET)	Same
Piston	Medical rubber	Polyisoprene rubber	Analysis 2
Patient-contact material-Connection tube			
Tube	polyvinyl chloride (PVC)	polyvinyl chloride (PVC)	Same
Luer connectors	Polycarbonate (PC)	Polycarbonate (PC)	Same
Patient-contact material-Spike and J shape tube			
Closure-piercing device	acrylonitrile-butadiene-styrene (ABS)	acrylonitrile-butadiene-styrene (ABS)	Same
Filter membrane	Medical rubber	Polypropylene (PP)	Analysis 2
J shape tube	Polyethylene (PE)	Polyethylene (PE)	Same

Analysis 1

Although the proposed device has more product specification than that of the predicate device, the performance test results of syringes meet the criteria of ISO 7886-1, ISO 594-1 and ISO 594-2. The performance test results of connection tube meet the criteria of ISO 594-1 and ISO 594-2. The performance test results of spike and J shape tube showed no leaks. Therefore the specification difference is considered not to affect the Substantially Equivalency (SE) between the proposed and predicate device.

Analysis 2

The patient contact material of piston and filter membrane for the proposed device is different from predicate device. However, the contact classification for the proposed device is same as the predicate device, both of them belong to blood path and indirect limited contact. In addition, biocompatibility tests which include Cytotoxicity, Irritation, Sensitization, Acute Toxicity, Hemolysis and Pyrogen have been evaluated for the proposed device and the test result does not show any adverse effects. Therefore, this difference is not considered to affect substantially equivalence.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison above, the proposed device, Sterile High-pressure Angiographic Syringes for Single-use, is determined to be Substantially Equivalent (SE) to the predicate device.