July 6, 2018

Shenyang MasTech Medical Device Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd
P.O.box 120-119
Shanghai, 200120 CN

Re: K172694
Trade/Device Name: Sterile Disposable Syringes
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: May 31, 2018
Received: June 5, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael John -S
2018.07.06 11:58:42 -04'00'

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172694

Device Name

Sterile Disposable Syringes

Indications for Use *(Describe)*

The Sterile Disposable Syringes are intended for the injection of contrast media or saline, they shall be used with an U.S legally marketed angiographic injector.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Exhibit #10 510(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: K172694

1. Date of Preparation: 05/29/2018

2. Sponsor Identification

Shenyang MasTech Medical Device Co., Ltd.
Zhaojia Village, Qianjin Street, Dadong District, Shenyang 110165, China

Establishment Registration Number: Not yet registered

Contact Person: Liu Han
Position: General Manager
Tel: +86-24-24331351
Fax: +86-24-24326101
Email: sy@mastech-medical.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 240-238-7587
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Sterile Disposable Syringes
Common Name: Disposable angiographic syringe

Regulatory Information

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

Intended Use Statement:

The Sterile Disposable Syringes are intended for the injection of contrast media or saline, they shall be used with an US legally marketed angiographic injector.

Device Description

The proposed devices are available in packs, which may include different configuration 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

Model (Syringe)	Volume (ml)	Type	K Number of Compatible Angiographic Injector
DSA-150-MARK	150ml	Single shot	K903390
DSA-150-LF	150ml	Single shot	K860204
DSA-130-NE	125ml	Single shot	K092896
CT/DSA-150-LF	150ml	Single shot	K963071, K873687
CT-200-MARK	200ml	Single shot	K993728, K991557, K982814, K934086, K924116, K913624
CT-200-MARK-E	200ml	Single shot	K071378, K063029, K011160
CT-200/200-MARK-E	200/200ml	Dual shoot	K071378, K063029, K031571
CT-200-LF	200ml	Single shot	K912944
CT-100-NE	100ml	Single shot	K133189, K071691, K062168, K052633
CT-200-NE	200ml	Single shot	K133189, K071691, K062168,

			K052633
CT/MRI-60-NE	50ml	Single shot	K133189, K091734 (MRI), K071691, K062168, K052633
MRI-60-LF	60/60ml	Dual shoot	K073592, K984088
MRI-60-MARK	65/65ml	Dual shoot	K011991, K935668
MRI-100-MARK	65/115ml	Dual shoot	K042784, K033247, K012950
MRI-100-EZEM	100/100ml	Dual shoot	K020892

The connecting tubes, which is used to connect the syringe and the catheter. The tubes are available in three configurations, which are straight tube, Type T tube and spiral tube. The different between these tubes is tube shape, which is available in straight shape for straight tube, spiral shape for spiral tube and T shape for T tube. The Type T tube is available in a various specifications to connect different model of syringe.

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: K072696
Product Name: ANT Angiographic Syringes
Manufacturer: Shenzhen Ant Hi-Tech Industrial 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:

Cleanliness	Clause 5 of ISO 7886-2:1996
Limits for acidity or alkalinity	Clause 6 of ISO 7886-2:1996
Limits for extractable metals	Clause 7 of ISO 7886-2:1996
Lubricant	Clause 8 of ISO 7886-2:1996
Tolerance on graduated capacity	Clause 9 of ISO 7886-2:1996
Graduated scale	Clause 10 of ISO 7886-2:1996
Barrel	Clause 11 of ISO 7886-2:1996
Piston/ plunger assembly	Clause 12 of ISO 7886-2:1996
Nozzle	Clause 13 of ISO 7886-2:1996
Performance	Clause 14 of ISO 7886-2:1996

Gauging	Clause 4.1 of ISO 594-1:1986
Liquid leakage	Clause 4.2 of ISO 594-1:1986
Air leakage	Clause 4.3 of ISO 594-1:1986
Separation force	Clause 4.4 of ISO 594-1:1986
Stress cracking	Clause 4.5 of ISO 594-1:1986

Gauging	Clause 4.1 of ISO 594-2:1998
Leakage	Clause 4.2 of ISO 594-2:1998
Separation force	Clause 4.3 of ISO 594-2:1998
Unscrewing torque	Clause 4.4 of ISO 594-2:1998
Ease of assembly	Clause 4.5 of ISO 594-2:1998
Resistance to overriding	Clause 4.6 of ISO 594-2:1998
Stress cracking	Clause 4.7 of ISO 594-2:1998

Sterile Barrier Packaging Testing performed on the proposed device:

Seal strength	ASTM F88/F88-09
Dye penetration	ASTM F1929-12

Sterilization and Shelf Life Testing performed on the proposed device:

EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Bacteria Endotoxin Limit	USP 38-NF 33 <85>
Shelf Life Evaluation	Physical, Mechanical, Chemical, Package Tests were performed on aging samples to verify the claimed shelf life of the device

Biocompatibility Testing:

The patient-contact materials of proposed devices are identified and the proposed devices were tested for Cytotoxicity (ISO 10993-5), Skin Sensitization (ISO 10993-10), Intracutaneous Reactivity (ISO 10993-10), Acute Systemic Toxicity (ISO 10993-11), Hemolytic Property (ASTM F756), Pyrogen (ISO 10993-11) and Complement Activity (ISO 10993-4).

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device			Predicate Device K072696		
Product Code	DXT			DXT		
Regulation Number	CFR 870.1650			CFR 870.1650		
Intended Use	The Sterile Disposable Syringes are intended for the injection of contrast media or saline, they shall be used with an U.S legally marketed angiographic injector.			ANT Angiographic Syringes are syringes for the injection of contrast media or saline. This syringe is for single use with U.S leally marketed angiographic injection.		
Operation mode	Power-driven operation, single use			Power-driven operation, single use		
Configuration and Material	Angiographic Syringe	Configuration	Material	Angiographic Syringe	Configuration	Material
		Barrel	Polycarbonate (PC) or Polypropylene (PP)		Barrel	Polypropylene (PP) or Polyethylene terephthalate (PET)
		Piston	Natural Rubber		Piston	Unknown
		Piston Seat	Polycarbonate (PC) or Polypropylene (PP)		Piston Seat	Unknown
		Protective Cap	Polypropylene (PP)		Protective Cap	Unknown
	Connecting tube	Tubing	Polyvinyl Chloride (PVC)	Connecting tube	Tubing	Unknown
		Check Valve	Polycarbonate (PC)		Check Valve	Unknown
	J shape tube		Polyethylene (PE)	J shape tube		Unknown
	Spike		Acrylonitrile-butadiene-styrene (ABS)	Spike		Unknown
Sterility	EO Sterilized			EO Sterilized		
Single Use	Yes			Yes		

Biocompatibility	Cytotoxicity	No cytotoxicity.	Cytotoxicity	No cytotoxicity.
	Irritation	No intracutaneous reactivity.	Irritation	No intracutaneous reactivity.
	Sensitization	No skin sensitization	Sensitization	No skin sensitization
	Systemic Toxicity	No systemic toxicity	Systemic Toxicity	No systemic toxicity
	Hemolysis	No hemolysis	Hemolysis	No hemolysis
	Pyrogen	No pyrogen	Pyrogen	No pyrogen
	Complement Activation	No complement	Complement Activation	No complement
Performance	Comply with ISO 7886-2, ISO594-1 and ISO 594-2		Comply with ISO 7886-2, ISO594-1 and ISO 594-2	

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate device.