December 12, 2017

Union Medical Shenzhen Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 CN

Re: K170279
Trade/Device Name: Disposable High Pressure Syringe
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: Class II
Product Code: DXT
Dated: November 21, 2017
Received: November 24, 2017

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Kenneth J. Cavanaugh -S

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)*

K170279

Device Name

Disposable High Pressure Syringe

Indications for Use *(Describe)*

The Disposable High Pressure Syringe is intended for the injection of contrast media or saline. This syringe is for single use and it shall be used 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.

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

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510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K170279

1. Date of Preparation: 11/14/2017

2. Sponsor Identification

Union Medical Shenzhen Co., Ltd.
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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Disposable High Pressure Syringe
Common Name: Disposable angiographic syringe
Models:
SMR101, SMR102, SMR103, SMR104, SMR201, SMR202, SMR203, SMR204, SMR301, SMR302, SLF101, SLF102, SLF201, SLF202, SLF301, SNE101, SNE102, SNE103, SNE104, SNE301 and SEZ101

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

Indications for Use:
The Disposable High Pressure Syringe is intended for the injection of contrast media or saline. This syringe is for single use and it shall be used with US legally marketed angiographic injectors.

Device Description
The Disposable High Pressure Syringe is available in packs, which may include different configurations of syringes and accessories, the accessories include connector tube, Quick fill tube and Spike.

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.

The connector tube is used to connect the syringe and the catheter. They are also available in three configurations, which are WLP Series tube with one syringe connector (used with single shot syringe), WLT Series tube and WLM Series tube with two syringe connectors (used with dual shot syringe). The three connector tubes can withstand maximum pressure of 350psi.

The Quick Fill Tube and the Spike is used to draw drug into the syringe.

The proposed devices 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.	Models (P/N)	Volume(ml)	Type	Applicable Injection Systems/510(k) Number
1	SMR101	200ml	Single Shot	MEDRAD Visitron CT 610 (K991557), En Vision CT Injection System (K993782)
2	SMR102	200ml	Single Shot	MEDRAD CT Stellant Injection System (K023183)
3	SMR103	125ml	Single Shot	MEDRAD Visitron CT 610 (K991557), En Vision CT Injection System (K993782)
4	SMR104	200/200ml	Dual Shots	MEDRAD CT Stellant Injection System (K023183)
5	SMR201	150ml	Single Shot	MEDRAD Mark V Injection System (K822536)
6	SMR202	200ml	Single Shot	MEDRAD Mark V Injection System (K822536)
7	SMR203	60ml	Single Shot	MEDRAD Mark V Injection System (K822536)
8	SMR204	130ml	Single Shot	MEDRAD Mark IV Injection System (K903390)
9	SMR301	60/60ml	Dual Shots	MEDRAD Spectris MR Injection System (K935668)
10	SMR302	110/60ml	Dual Shots	MEDRAD Solaris MR Injection System (K033247)
11	SLF101	200ml	Single Shot	LF CT9000 Injection System (K912944)
12	SLF102	200/200ml	Dual Shots	LF OptiVantage Dual-Head Injection System (K042744)
13	SLF201	150ml	Single Shot	LF Angiomat 6000 Injection System (K944875)
14	SLF202	150ml	Single Shot	LF Angiomat Illumena Injection System (K963071)
15	SLF301	60/60ml	Dual Shots	LF MRI OPTISTAR Injection System (K984088)
16	SNE101	100ml	Single Shot	NEMOTO Dual Shot ALPHA7 Injection System (K133189)
17	SNE102	200ml	Single Shot	NEMOTO Dual Shot ALPHA7 Injection System (K133189)
18	SNE103	200/60ml	Dual Shots	Nemoto Dual Shot CT Injection System (K052633)
19	SNE104	200/100ml	Dual Shots	Nemoto Dual Shot CT Injection System (K052633)
20	SNE301	60/60ml	Dual Shots	NEMOTO MRI Injection System (K091734)
21	SEZ101	200ml	Single Shot	EZEM Empower CT Injection System (K063029)

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 F 88/F88M-2015 Standard test method for seal strength of flexible barrier materials;
- ASTM F1140/F1140M-13 Standard test methods for internal pressurization failure resistance of unrestrained packages;
- USP37-NF32 <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
- ISO594-1:1986 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General Requirements;
- ISO594-2:1998 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock Fitting;
- ISO 10993-4:2002 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood;
- 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 10993-11:2006 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity;

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 K151960
Product Code	DXT	DXT
Regulation Number	CFR 870.1650	CFR 870.1650
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.	High-pressure Angiographic Syringes for Single-use are syringes for the injection of contrast media or saline. This syringe is for single use with US legally marketed angiographic injectors.
Mode of operation	Power-driven operation, single use	Power-driven operation, single use
Configuration	Angiographic Syringe	Angiographic Syringe
	Connector tube	Connecting tube
	Quick Fill Tube/Spike	J shape tube/Spike
Sterility	EO Sterilized	EO Sterilized
Single Use	Yes	Yes
Performance	Comply with: ISO 7886-2 ISO 594-1 ISO 594-2	Comply with: ISO 7886-2 ISO 594-1 ISO 594-2
Biocompatibility	Conforms to the requirements of ISO 10993 series Standards	Conforms to the requirements of ISO 10993 series Standards

9. Substantially Equivalent (SE) Conclusion

Based on the comparison, the intended use, mode of operation, configuration, sterility of proposed device is determined to be Substantially Equivalent (SE) to the predicate device.

In addition, the results of performance tests performed on the proposed device can also demonstrate the proposed device is complied with FDA recognized standards, which the predicate device was also complied with. The results of biocompatibility studies performed on the proposed device demonstrate that the patient materials used in proposed device are biocompatible.

Based on the comparison above, the proposed device, Disposable High Pressure Syringe, is determined to be Substantially Equivalent (SE) to the predicate device.