October 10, 2018

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

Re: K182289
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: August 3, 2018
Received: August 23, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Lydia S. Glaw -S
2018.10.10 14:25:31 -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)*

K182289

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

Indications for Use *(Describe)*
Sterile High-pressure Angiographic Syringes for Single-use are intended for the injection of contrast media or saline; they shall be used with an 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 is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K182289

1. Date of Preparation: 9/28/2018

2. Sponsor Identification

Shenzhen Baoan Medical Supplies Co., Ltd
No. 6, Shenkeng Road, Shenkeng Industrial Zon Liuyue Community, Henggang, Longgang District, Shenzhen, 518173, China

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Chengyu Wang (Alternative Contact Person)

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Tel: +86-21-22815850,
Fax: 001-3609253199
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;
Models: 100104 and 100114

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:
Sterile High-pressure Angiographic Syringes for Single-use are intended for the injection of contrast media or saline; they shall be used with an US legally marketed angiographic injectors.

Device Description:
The proposed devices include 2 models of plastic, disposable syringes and 5 connection tubes of different specifications. 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	Resistant Liquid Leak Pressure (psi)	Compatible Angiographic Injector
100104	200	Single Shot	400	CT 9000 & CT9000 ADV, K912944
100114	200/200	Dual Shot	400	CT 9000 & CT9000 ADV, K912944

The connection tubes are used to connect the syringe and the catheter. The tubes are also available in three configurations, which are straight tube (used with single shot syringe), type Y and type T tube (used with dual shot syringe), they can withstand maximum pressure of 400 psi.

The proposed devices are used with the J shape tube / spike cleared in K151960.

5. Identification of Predicate Device

510k 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 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 6% (Luer) taper for syringes, needles and certain other medical equipment- Part 2: Lock fittings

ISO 7886-1:2017 Sterile hypodermic syringes for single use- Part 1: Syringes for manual use;

ISO 7886-2:1996 Sterile hypodermic syringes for single use- Part 2: Syringes for use with power-driven syringe pumps.

The test samples of syringe 100104 and 100114 with accessories are tested for liquid leakage and flow characteristics. Actually, there is no design change between proposed device and predicate, the testing using 400 psi pressure is to demonstrate the increased resistant liquid leakage pressure statement. Therefore, other testing is not necessary for this submission.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent Comparison

Table 2 Substantially Equivalent Comparison

ITEM	**Proposed Device**	**Predicate Device, K151960**
Product Code	DXT	DXT
Regulation No.	21 CFR 870.1650	21 CFR 870.1650
Class	II	II
Indications for Use	Sterile High-pressure Angiographic Syringes for Single-use are intended for the injection of contrast media or saline; they shall be used with an US legally marketed angiographic injectors.	Sterile High-pressure Angiographic Syringes for Single-use are intended for the injection of contrast media or saline; they shall be used with an US legally marketed angiographic injectors.
Mode of Operation	Power-driven operation, single use	Power-driven operation, single use

Configuration	Angiographic Syringe	Angiographic Syringe
	Connection Tube	Connection Tube
	/	J shape tube/Spike
Sterility	EO Sterilized	EO Sterilized
Single Use	Yes	Yes
Resistant Liquid Leak Pressure (psi)	Syringe: 400 psi	Syringe: 300 psi
	Connection Tube: 400 psi	Connection Tube: 300 psi
Other Performance	Comply with ISO 7886-1, ISO 7886-2, ISO 594-1 and ISO 594-2	Comply with ISO 7886-1, ISO 7886-2, ISO 594-1 and ISO 594-2
Biocompatibility	Conforms to the requirements of ISO 10993 series Standards	Conforms to the requirements of ISO 10993 series Standards

The proposed devices are stated to have a higher resistant liquid leak pressure. For this modification, liquid leak testing has been conducted on the models in this submission and test results have demonstrated the resistant liquid leak pressure is 400 psi for syringes and connection tube. Therefore, this modification will not impact the safety and effectiveness of device. In addition, the modified devices only include angiographic syringe and connection tube and they should be used with the J shape tube/spike cleared in K151960.

9. Substantially Equivalent (SE) Conclusion

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