August 7, 2020

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

Re: K192657
Trade/Device Name: Sterile High-pressure Angiographic Syringes for Single-use
Regulation Number: 21 CFR 870.1650
Regulation Name: Injector And Syringe, Angiographic
Regulatory Class: Class II
Product Code: DXT
Dated: July 1, 2020
Received: July 13, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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: K192657

1. Date of Preparation: 8/5/2020

2. Sponsor Identification

Shenzhen Boon Medical Supply Co., Ltd.
No.18 Jirong Road, Shenkeng, Henggang Street, Longgang District Shenzhen Guangdong, China 518173

Establishment Registration Number: 3012395857
Contact Person: Mingan Mu
Position: General Manager
Tel: +86-755-28638515
Fax: +86-755-28638033
Email: boon@szboon.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Lee Fu (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 High-pressure Angiographic Syringes for Single-use
Common Name: Disposable angiographic syringe
Models:

Product Name	Models
Syringe	100101, 100103, 100113, 200101, 200102, 300101, 300105, 100104, 100114, 200103, 300103,100111, 100121, 100124, 200104, 100108, 100118, 100129, 100130,100109, 100119, 200107, 300102, 300108, 300110, 300111, 300112
Connection Tube	400101, 400102, 400103, 600101, 600102, 500105, 500106, 500107, 500108, 400201, 400202, 400203, 600201, 600202, 500101, 500102, 500103, 500104, 500201, 500202, 500203, 500204, 500205, 500206, 500207, 500208
J shape tube	700103
Spike	700101, 700102, 700104-1, 700104-2, 700105-1, 700105-2, 700106, 700107-1, 700107-2

Regulatory Information

Classification Name: Injector And Syringe, Angiographic
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 device is intended for the injection of contrast media or saline. It includes disposable syringes, connection tube, J shape tube and spike.

- Syringe: the syringe are intended to be used with an U.S. legally marketed angiography injector. Compatibility are shown in Table 1.

Table 1 Compatibility between Syringe and Injectors

Model (Syringe)	Volume (ml)	Type	Resistant liquid leak pressure (psi)	Injector
100101	200ml	Single Shot	400	MCT & MCT plus CT, K924116 Vistron CT, K991557 EnVision CT, K934086
100103	200ml	Single Shot	400	Stellant-S K182273
100113	200/200ml	Dual Shots	400	Stellant-D, K182273
200101	65/65ml	Dual Shots	300	Spectris, K935668
200102	65/115ml	Dual Shots	300	Solaris MRI, K033247
300101	150ml	Single Shot	1200	Mark V, K822536
300105	130ml	Single Shot	1200	Mark III & Mark IV, K822536
100104	200ml	Single Shot	400	CT 9000 & CT9000 ADV, K912944
100114	200/200ml	Dual Shots	400	CT 9000 & CT9000 ADV, K912944
200103	60/60ml	Dual Shots	300	Optistar LE, Elite, K073592
300103	150ml	Single Shot	1200	ILLUMENA, K963071
100111	200ml	Single Shot	400	Empower CT, K071378
100121	200/200ml	Dual Shots	400	Empower CT, K071378
100124	60/100ml	Dual Shots	400	Dual Shot, K052633
200104	60/60ml	Dual Shots	300	Sonic Shot, K091734
100108	200ml	Single Shot	400	Dual shot CT, K062168
100118	200/200ml	Dual Shots	400	Dual shot CT, K133189
100129	125ml	Single Shot	400	CT Optione, K152361
100130	125/125ml	Dual Shots	400	CT Optione, K152361
100109	100ml	Single Shot	400	Dual shot, K062168
100119	100/100ml	Dual Shots	400	Duat shot, K062168
200107	100/100ml	Dual Shots	300	EZEM Empower, K062449
300102	125ml	Single Shot	1200	120S, K092896
300108	150ml	Single Shot	1200	Mark VII , K112086
300110	150ml	Single Shot	1200	Rempress,K092896
300111	150ml	Single Shot	1200	Angiomat 6000, K944875
300112	200ml	Single Shot	1200	Illumena K963071

- Connection tube: it is used to connect the syringe and the catheter. The tubes are also available in various configurations, which are straight tube (used with single shot syringe), type Y and type T tube (used with dual shot syringe). The pressure specification for connection tube is provided in *Table 2 Pressure Specifications for Connection Tube*.

Table 2 Pressure Specifications for Connection Tube

Model	Maximum Withstanding Pressure (psi)	Type
400101	400	Straight
400102	400	Type Y
400103	400	Type T
600101	400	Type T
600102	400	Type Y
500105	1200	Straight
500106	1200	Straight
500107	1200	Straight
500108	1200	Straight
400201	400	Straight
400202	400	Type Y
400203	400	Type T
600201	400	Type T
600202	400	Type Y
500101	1200	Straight
500102	1200	Straight
500103	1200	Straight
500104	1200	Straight
500201	1200	Straight
500202	1200	Straight
500203	1200	Straight
500204	1200	Straight
500205	1200	Straight
500206	1200	Straight
500207	1200	Straight
500208	1200	Straight

- J shape tube: it is used to draw contrast media/saline into the syringe barrel before the syringe installed.

- Spike: it is used to draw contrast media/saline into the syringe barrel before the syringe installed. The pressure specification for spike is provided in *Table 3 Pressure Specifications for Spike*

Table 3 Pressure Specifications for Spike

Model	Maximum Withstanding Pressure (psi)	Type
700101	/	Long spike
700102	/	Short spike
700104-1	400 psi	Single Air Chamber Transfer Set
700104-2	400 psi	Single Air Chamber Transfer Set with Extension Tube
700105-1	400 psi	Dual Air Chamber Tranfer Set
700105-2	400 psi	Dual Air Chamber Tranfer Set with extension tube
700106	/	Transfer Set With C-Clamp
700107-1	/	Transfer set with Clave connector
700107-2	/	Clave connector Transfer set with Check valve

5. Identification of Predicate Device

510(k) Number: K151960
Product Name: Sterile High-pressure Angiographic Syringes for Single-use
Manufacturer: Shenzhen Boon Medical Supply 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-15Standard test method for seal strength of flexible barrier materials;
- ASTM F1929-15Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration;

- USP 41-NF36 2018 <85> Bacterial Endotoxins Limit;
- 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 items include Lubricant weight, Graduated capacity tolerance, overall length of scale, syringe dimension, nozzle lumen, dead space, liquid leakage, air leakage and flow characteristics
- ISO594-1:1986 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment –Part 1: General Requirements;

  The test items include Gauging test, liquid leakage, air leakage, separation force and stress cracking
- ISO594-2:1998 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment –Part 2: Lock Fitting;

  The test items include Liquid leakage, air leakage, separation force, unscrew torque, ease of assembly, resistance to overriding and stress cracking
- 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 10993-4:2017, Biological Evaluation of Medical Device –Part 4: Selection of tests for interactions with blood.
- ASTM F756:2017, Standard Practice for Assessment of Hemolytic Properties of Materials
- USP 41 NF 36<151> Pyrogen Test
- ISO 11134:2014, Sterilization of health-care Products-Ethylene Oxide-Requirements for the development, validation and routine control of a sterilization process for medical devices
- USP <788> Particular Matter in Injections
- Compatibility Test Report between injectors, syringe, connection tube and spike/J shape tube. The compatibility test demonstrated that each device meets performance under maximum sustained pressure specification.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 4 Comparison of Technology Characteristics

Item		Proposed Device	Predicate Device K151960	Comments
Product Code		DXT	DXT	Same
Regulation Number		CFR 870.1650	CFR 870.1650	Same
Indications for Use		The proposed device, 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.	Same
Prescription only (Rx)		Prescription only (Rx)	Prescription only (Rx)	Same
Mode of operation		Power-driven operation, single use	Power-driven operation, single use	Same
Configuration		Angiographic Syringe	Angiographic Syringe	Same
		Connecting tube	Connecting tube	Same
		J shape tube/Spike	J shape tube/Spike	Same
Sterility		EO Sterilized	EO Sterilized	Same
Single Use		Yes	Yes	Same
Maximum withstanding pressure	Syringe	300psi, 400psi, 1200psi	300psi, 1200psi	Difference #1
	Connection tube	300psi, 400psi, 1200psi	300psi, 1200psi	Difference #1
	J shape tube	/	/	Same
	Spike	400 psi	/	Difference #1
Specification	Syringe (Volume, ml)	200, 150, 125, 130, 100, 200/200, 60/100, 125/125, 100/100, 65/65, 65/115, 60/60, 50/50	200, 150, 130, 200/200, 60/100, 65/65, 65/115, 60/60, 50/50,	Difference #2
	Connection tube (overall Length, mm)	200~2500, 1500~2500, 1500, 1800, 2000, 2500, 500, 750, 1000, 1200	1500, 1800, 500, 750, 1000, 1200	Difference #2
	J shape tube (overall Length, mm)	240	240	Same
	Spike (overall Length,	58.8, 47.3, 1000, 2800, 1200, 2900, 180, 260, 340, 420, 500,	58.85, 47.35	Difference #2

	mm)	450, 550, 600		
Performance				
Syringe		ISO 7886	ISO 7886	Same
Luer connector		ISO 594-1; ISO 594-2	ISO 594-1; ISO 594-2	Same
Compatibility		Pass	Pass	Same
Patient-Contact Material				
Syringe	Barrel	PP (polypropylene) or PET (Polyethylene terephthalate)	PP (polypropylene) or PET (Polyethylene terephthalate)	Same
	Piston	Polyisoprene rubber	Polyisoprene rubber	Same
	Lubricant	Polydimethylsiloxane	Polydimethylsiloxane	Same
Connection tube	Tubing	PVC (Polyvinylchloride with DEHP) or PVC (Polyvinylchloride without DEHP) or PU (Polyurethane)	PVC (Polyvinylchloride) or PU (Polyurethane）	Difference #3
	Luer connectors	PC (Polycarbonate)	PC (Polycarbonate)	Same
	UV adhesive	Ultraviolet adhesive	Ultraviolet adhesive	Same
Spike	Closure-piercing device	ABS (acrylonitrile-butadiene-styrene)	ABS (acrylonitrile-butadiene-styrene)	Same
	Filter membrane	PP (polypropylene)	PP (polypropylene)	Same
	Tube	Polyvinyl chloride (PVC)	/	Difference #3
	Luer Connector	Polycarbonate (PC)		
	Protective cap	Acrylonitrile-butadiene-styrene (ABS)		
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
Shelf Life		5 year	3 year	Difference #4

Substantial Equivalence Discussion

Difference #1 – Maximum withstanding pressure

The maximum withstanding pressure for syringe, connection tube and spike of proposed device is different from the predicate device. However, the Conical Lock Fitting Performance Test and Compatibility Test were performed on the proposed device and the test result demonstrated that the

syringe, connection tube and spike can withstand the stated maximum pressure. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Difference #2 – Specification

The specification for volume of syringe, length of connection tube and spike is different from the predicate device. However, the different specifications will be selected by physician per surgical condition. In addition, the difference in syringe volume were addressed through ISO 7886 performance testing. The compatibility test and pressure test were performed on connection tube and spike and the test results demonstrated that the different length of connection tube and spike will not cause pressure leakage. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Difference #3 – Patient-Contact Material

The patient-contact material for connection tube and spike of proposed device is different from the predicate device. The material of tubing of connection tube for proposed device, which is made of PVC (Polyvinylchloride without DEHP) or PU (Polyurethane), is the same as the material of tubing of Connection tube for predicate device, which is also manufactured by Shenzhen Boon Medical Supply Co., Ltd. In addition, the biocompatibility test was performed on the syringe, connection tube which is made of PVC (Polyvinylchloride with DEHP) and spike. The test results demonstrated that the proposed device does not raise the adverse effect on the material. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Difference #4 – Shelf Life

The shelf life of the proposed device is different from predicate device. However, the shelf life tests were performed on the proposed device after accelerated aging and the test results demonstrated that the proposed device has a five-year shelf life. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

9. Substantially Equivalent (SE) Conclusion

The results of performance tests performed on the proposed device can demonstrate the proposed devices are complied with FDA recognized standards, which the predicate device 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, Sterile High-pressure Angiographic Syringes for Single-use, is determined to be Substantially Equivalent (SE) to the predicate device.