August 22, 2024

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

Re: K241109
Trade/Device Name: Single-use Sterile High-pressure Angiographic Syringes and Accessories
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: July 20, 2024
Received: July 22, 2024

Dear Shengyu Fan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shruti N. Mistry -S

Shruti Mistry
Assistant Director
Division of Drug Delivery and General
Hospital Devices, and Human Factors
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241109

Device Name
Single-use Sterile High-pressure Angiographic Syringes and Accessories

Indications for Use *(Describe)*
Single-use Sterile High-pressure Angiographic Syringe and Accessories are intended for the injection of contrast media or saline, they shall be used with U.S. 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.

1. **Date of Preparation**: March 3, 2024

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

Establishment Registration Number: 3012395857 Contract Person: Gui Wenjuan

Position: Management Representative Tel: +86-755-28638515

Fax: +86-755-28638033
E-mail: guiwenjuan@szboon.com

Subject Device Information:

The assigned 510(k) Number: K241109
Trade Name: Single-use Sterile High-pressure Angiographic Syringes and Accessories
Common Name: Disposable angiographic syringe Models

Regulatory Information:

Classification Name: Injector And Syringe, Angiographic Classification: II
Product Code: DXT
Regulation Number: 21 CFR 870.1650 Review Panel: General Hospital

3. **Identification of Predicate Device**

510(k) Number: K211564
Product Name: Sterile High-pressure Angiographic Syringes for Single-use Manufacturer: Shenzhen Boon Medical Supply Co., Ltd.

4. Designated Submission Correspondent Shengyu Fan (Primary Contact Person) E-mail:

faguibu07@szboon.com

DARCO International Co., Ltd.

510 Shotgun Rd. Suite 520, Sunrise, FI 33326

Tel: 954-380-8595

Fax: 877-804-4505

510(K) Summary
E-mail: ahr@darcointernational.net

510(K) Summary

5. Description of Proposed Device

Product Name	Models
Syringe	100101, 100103, 100113, 200101, 200102, 300101, 300105, 100104, 100114, 200103, 300103, 100111, 100121, 100123, 100124, 100125, 200104, 100108, 100118, 100129, 100130, 100109, 100119, 200107, 300102, 300108, 300110, 300111, 300112, 100110, 100120, 100112, 100122, 300107, 200105, 200113, 200110, 200111
Connection Tube	400101, 400102, 400103, 600101, 600102, 500105, 500106, 500107, 500108, 400201, 400202, 400203, 400204, 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, 700204-1, 700204-2, 700205-1, 700205-2, 700206, 700207-1, 700207-2

Indications for Use:
Single-use Sterile High-pressure Angiographic Syringe and Accessories are intended for the injection of contrast media or saline, they shall be used with U.S. 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 syringes are intended to be used with an U.S. legally marketed angiographic injector.

Compatibility is shown in the *Table 1 Compatibility between Syringe and Injectors*. (Note: the newly added and the difference between K211564 and the proposed device is highlighted in Red.)

510(K) Summary

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 CT OptiVantage, K063503
100114	200/200ml	Dual shots	400	CT 9000&CT9000 ADV, K912944 CT OptiVantage, K063503
200103	60/60ml	Dual shots	300	Optistar LF, 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
100123	100/200ml	Dual shots	400	Dual Shots, K052633 Dual shots Alpha, K062168
100124	60/100ml	Dual shots	400	Dual Shots, K052633 Dual shots Alpha, K062168
100125	60/200ml	Dual shots	400	Dual Shots, K052633 Dual shots Alpha, K062168
200104	60/60ml	Dual shots	300	Sonic Shot, K091743
100108	200ml	Single shot	400	Dual shots CT, K062168 Dual shots Alpha, K062168
100118	200/200ml	Dual shots	400	Dual shots CT, K133189 Dual shots Alpha, K062168
100129	125ml	Single shot	400	CT Optione, K152361 CT OptiVantage, K063503 CT 9000&CT 9000ADV, K912944
100130	125/125ml	Dual shots	400	CT Optione, K152361 CT OptiVantage, K063503 CT 9000&CT 9000ADV, K912944

100109	100ml	Single shot	400	Dual Shots, K062168 Dual shots Alpha, K062168
100119	100/100ml	Dual shots	400	Dual Shots, K062168 Dual shots Alpha, K062168
200107	100/100ml	Dual shots	300	EZEM Empower MR, K062449
300102	125ml	Single shot	1200	120S, K092896
300108	150ml	Single shot	1200	Mark VII, K122086
300110	150ml	Single shot	1200	Rempress, K092896
300111	150ml	Single shot	1200	Angiomat 6000, K944875
300112	200ml	Single shot	1200	Illumena, K963071
100110	200ml	Single shot	400	Medrad V Plus, K903390
100120	200/200ml	Dual shots	400	Medrad V Plus, K903390
100112	200ml	Single shot	400	Accutron CT& Accutron CT-D
100122	200/200ml	Dual shots	400	Accutron CT-D
300107	200ml	Single shot	1200	Accutron HP& Accutron HP-D
200105	65/65ml	Dual shots	300	Accutron MR,
200113	65/200ml	Dual shots	300	Accutron MR,
200110	65/115ml	Dual shots	300	Medrad MRXperion, K182276
200111	115ml	Single shot	300	Spectris&Solaris, K033247

Connection tube: it is used to connect the syringe and the catheter. The tubes (extension tube) are also available in various configurations, which are Type B (used with single shot syringe, highlighted in Red mark), renamed “Straight tube” to “Type B” and added a new model (400204) connecting tube in the Table. The product structure, manufacturing process, product materials have not changed. Type Y and type T tube are used with dual shots syringe. The pressure specification for connection tube is provided in *Table 2 Pressure Specifications for Connection Tube*. (Note: the newly added and the difference between K211564 and proposed device is highlighted in Red)

Table 2 Pressure Specifications for Connection Tube

Model	Maximum Withstanding Pressure (psi)	Type
400101	400	Type B
400102	400	Type Y
400103	400	Type T
600101	400	Type T
600102	400	Type Y
500105	1200	Type B

500106	1200	Type B
500107	1200	Type B
500108	1200	Type B
400201	400	Type B
400202	400	Type Y
400203	400	Type T
400204	400	Type B
600201	400	Type T
600202	400	Type Y
500101	1200	Type B
500102	1200	Type B
500103	1200	Type B
500104	1200	Type B
500201	1200	Type B
500202	1200	Type B
500203	1200	Type B
500204	1200	Type B
500205	1200	Type B
500206	1200	Type B
500207	1200	Type B
500208	1200	Type B

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

Spike: it is used to draw contrast media/saline into the syringe barrel before the syringe installation. The pressure specification for the spike is provided in the following table as *Table 3 Pressure Specifications for Spike* (Note: this model is only used to distinguish whether it is made with or without DEHP). The product materials, manufacturing process and product structure have not changed. Spikes not made with DEHP are marked with Red. The new additions of spike models are: 700204- 1, 700204-2,700205-1, 700205-2, 700206, 700207-1, 700207-2)

Table 3 Pressure Specifications for Spike

Model (contains DEHP) Original	Model (not made with DEHP) New added	Maximum Withstanding Pressure (psi)	Type
700101	/	/	Long Spike
700102	/	/	Short Spike
700104-1	700204-1	400	Single Air Chamber Transfer Set

700104-2	700204-2	400	Single Air Chamber Transfer Set with Extension Tube
700105-1	700205-1	400	Dual Air Chamber Transfer Set
700105-2	700205-2	400	Dual Air Chamber Transfer Set with Extension Tube
700106	700206	/	Transfer Set with C-Clamp
700107-1	700207-1	/	Transfer Set with Clave Connector
700107-2	700207-2	/	Clave connector ansfer set with Check valve

6. Non-Clinical Test Conclusion

Nonclinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

ISO 10993-7:2008 Biological evaluation of Medical device- Part 7: Ethylene oxide sterilization residuals;
ASTM F88/F88M-23 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-NF<85> Bacterial Endotoxin Limit;
ISO 7886-1: 2017 Sterile hypodemic syringes for Single-use-Part 1: Syringes for manual use;
ISO 7886-2: 2020 Sterile hypodemic 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;

ISO 80369-7: 2021 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications ISO 10993-5: 2009 Biological evaluation of medical devices-Part 5: Tests for In Vitro Cytotoxicity;
ISO 10993-10:2021 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-NF <151> Pyrogen Test
Compatibility Test Report includes information between injectors, syringe, connection tube and spike/J shape tube. The compatibility test demonstrated that each device meets performance

under maximum sustained pressure specifications.

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 K241109**	**Predicate Device K211564**	**Comments**
Product Code	DXT	DXT	Same
Regulation Number	CFR 870.1650	CFR 870.1650	Same
Indications for Use	The proposed device, Single-use Sterile High-pressure Angiographic Syringes and Accessories are intended for the injection of contrast media or saline, they shall be used with U.S. legally marketed angiographic injectors.	The predicate 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	Different 1
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
	Connection tube	Connection tube	Same

510(K) Summary

	J shape tube/ Spike	J shape tube/ Spike	Same
Sterility	EO Sterilized	EO Sterilized	Same
Single Use	Yes	Yes	Same
Syringe	300psi, 400psi, 1200psi	300psi, 400psi, 1200psi	Same
Connection tube	300psi, 400psi, 1200psi New model added (400204).	300psi, 400psi, 1200psi	Different 2
J shape tube	/	/	/
Spike	400psi	400psi	Same
Syringe Specification (Volume/ ml)	200, 150, 125, 130, 100, 200/200, 60/100, 125/ 125, 100/100, 65/65, 65/ 115, 60/60, 50/50, 100/200, 115, 65/200 11 new models added.	200, 150, 125, 130, 100, 200/200, 60/100, 125/125, 100/100, 65/65, 65/115, 60/60, 50/50	Different 3
Connection tube Specification (overall length,mm)	200~2500, 1500~2500, 1500, 1800, 2000, 2500, 500, 750, 1000, 1200	200~2500, 1500~2500, 1500, 1800, 2000, 2500, 500, 750, 1000, 1200	Same
J shape tube Specification (overall length, mm)	240	240	Same

Spike Specification (overall length,mm)		58.8,47.3, 1000,2800, 1200,2900, 180,260,340,420,500,450,550,600	58.8,47.3, 1000,2800, 1200,2900, 180,260,340,420,500,450,550,600	Same
Performance				
Syringe		ISO 7886	ISO 7886	Same
Luer connector		ISO 80369-7	ISO 80369-7	Same
Compatibility		Pass	Pass	Same
Patient-Contact Material				
Syringe	Barrel	PP (Polypropylene) or PET (Polyethylene terephthalate)	PP (Polypropylene) or PET (Polyethylene terephthalate)	Same
Syringe	Piston	Polyisoprene rubber	Polyisoprene rubber	Same
Syringe	Lubricant	Polydimethylsiloxane	Polydimethylsiloxane	Same
Connection tube	Tubing	PVC (Polyvinylchloride with DEHP) or PVC (Polyvinylchloride without DEHP) or PU (Polyurethane)	PVC (Polyvinylchlori de with DEHP) or PVC (Polyvinylchloride without DEHP) or PU (Polyurethane)	Same
Connection tube	Luer connectors	PC (Polycarbonate)	PC (Polycarbonate)	Same
Connection tube	UV adhesive	Ultraviolet adhesive	Ultraviolet adhesive	Same

Spike	Closure-piercing device	ABS (acrylonitrile-butadiene -styrene)	ABS (acrylonitrile-butadiene -styrene)	Same
Spike	Filter membrane	PP (polypropylene)	PP (polypropylene)	Same
Spike	Tube	Polyvinyl chloride (PVC)	Polyvinyl chloride (PVC)	Same
Spike	Luer connector	carbonate (PC)	carbonate (PC)	Same
Spike	Protective cap	Acrylonitrile-butadiene -styrene (ABS)	Acrylonitrile-butadiene -styrene (ABS)	Same
J shape 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	5 -year	Same

510(K) Summary

9. Equivalence Discussion:

Different #1: Compared to the predicate device, the proposed device changed the product name from Sterile High-pressure Angiographic Syringes for Single-use to: Single-use Sterile High-pressure Angiographic Syringes and Accessories. The indications for use of the product share the same contents.

Different #2: Compared to the predicate device, a new connection tube model 400204 is introduced to the proposed device. Model 400204 is almost identical to 400202, the only difference is that the former has one more check valve than the latter. And the materials, manufacturing process, pressure rating (up to 400 psi, see compatibility test report), wall thickness (0.70±0.05mm) and length (200mm - 2500 mm) of 400204 are the same with the existing models of 400201, 400202 and 400203. The results of performance tests completed on the proposed device demonstrate that the proposed devices comply 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 the proposed device are biocompatible

Different #3: Compared the predicated device, the specifications of syringes have added 115ml, 100/200ml and 65/200ml in the proposed device, and the compatibility table between the proposed device and predicate device are shown in Table 1. The difference and the newly added devices are marked in Red.
The results of performance tests completed on the proposed device demonstrate that the proposed devices comply 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 the proposed device are biocompatible.

10. Substantial Equivalence Conclusion:

Based on the comparison above, the differences between the subject and predicate devices do not raise any new or different questions of safety and effectiveness when compared to the predicate device. The proposed device, Single-use Sterile High Pressure Angiographic Syringes and Accessories is determined to be Substantially Equivalent (SE) to the predicate device.