July 23, 2021

Shinva Ande Healthcare Apparatus Co., Ltd.
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.
FangShan District, BeiJing 102401
China

Re: K202060
Trade/Device Name: Disposable IV catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: June 17, 2021
Received: June 22, 2021

Dear Ray Wang:

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,

Payal Patel
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202060

Device Name
Disposable IV catheter

Indications for Use *(Describe)*
Disposable IV catheter is intended to be inserted into a Patient's peripheral vascular system for short term use to sample blood, monitor blood pressure, or administer fluids. These devices may be used for any patient population with consideration given to adequacy of vascular anatomy, procedure being performed, fluids being infused, and duration of therapy. The 22-18 GA devices are suitable for use with power injectors set to a maximum pressure of 300 psi when access ports not suitable for use with power injectors are removed.

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."

K202060 510(k) Summary

Date of Preparation: 7/19/2021

Sponsor Identification

Shinva Ande Healthcare Apparatus Co., Ltd.
No.77 Development Zone North Road, Zibo, Shandong 255086, China
Contact Person: Liang wanjie
Position: Registrar
Tel: +86-533-3917816
Fax: +86-533-3917815
Email: liangwanjie@andemed.com

Designated Submission Correspondent

Mr. Ray Wang

Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd., FangShan District, BeiJing, China 102401

Tel: +86-18910677558
Fax: +86-10-52214696
Email: ray.wang@believe-med.com

Subject Device

Trade Name:	Disposable IV Catheter
Regulation Name:	Catheter, Intravascular, Therapeutic, Short-term less than 30 days
Regulation Name:	21 CFR 880.5200
Product Code:	FOZ
Device Class:	Class II

Predicate Device: K183399, Nexiva IV Catheter System

Device Description

a. The Safety Straight IV Catheter System is a safety device designed to minimize blood exposure. It includes a passive needle-shielding mechanism designed to reduce accidental needle stick injury. The system consists of the following key parts: protector, needle, catheter, catheter hub, wedge, catheter hub wings, needle hub, vent fitting, safety clip, lid, valve tube, actuator, anti-reflux valve.
b. Straight IV Catheter System is the same as The Safety Straight IV Catheter System except for the safety device designed to minimize blood exposure.
c. Safety Closed IV Catheter System is a safety device designed to minimize blood exposure. It includes a passive needle-shielding mechanism designed to reduce accidental needlestick injury. The closed system is designed to keep blood contained within the device throughout the insertion process, which may prevent potential exposure for clinicians and patients. The system consists of the following key parts: protector, needle, catheter, catheter hub, wedge, catheter hub wings, septum, needle hub, safety clip, needle shield, extension tubing, pinch clamp, Luer adapter with single port, vent fitting, heparin plug, needleless connector, Luer adapter with dual port.
d. Closed IV Catheter System is the same as Safety Closed IV Catheter System except for the safety device designed to minimize blood exposure. The 18-22 gauge catheter systems are capable of withstanding high pressure injection procedures.
e. Needleless Safety Closed IV Catheter System is a safety device designed to minimize blood exposure. It includes a passive needle-shielding mechanism designed to reduce accidental needlestick injury. The closed system is designed to keep blood contained within the device throughout the insertion process, which may prevent potential exposure for clinicians and patients. The system consists of the following key parts: protector, needle, catheter, catheter hub, wedge, catheter hub wings, septum, needle hub, safety clip, needle shield, extension tubing, pinch clamp, Luer adapter with single port, vent fitting, needleless connector, Luer adapter with dual port.
f. Needleless Closed IV Catheter System is the same as Needleless Safety Closed IV Catheter System except for the safety device designed to minimize blood exposure. The 18-22 gauge catheter systems are capable of withstanding high pressure injection procedures.

Model(s):

Categories	Model	Model mark
Straight IV Catheter System	Type with wings but without injection port	IVC01
	Type without wings and injection port	IVC03
	Type with wings and injection port	IVC04
	Pen type	IVC05
Safety Straight IV Catheter System	Safety type with wings but without injection port	IVC06
	Safety type without wings and injection port	IVC07
	Safety type with wings and injection port	IVC08

	Safety pen type	IVC09
	Safety anti-reflux type	IVC02
Closed IV Catheter System	Closed type with single port	IVC10
	Closed type with dual port	IVC11
Safety Closed IV Catheter System	Safety closed type with single port	IVC12
	Safety closed type with dual port for Heparin plug and Needleless connector	IVC13
	Safety closed type with dual port for two Heparin plug	IVC14
Needleless Closed IV Catheter System	Needleless closed type with single port	IVC15
	Needleless closed type with dual port	IVC16
Needleless Safety Closed IV Catheter System	Needleless safety closed type with single port	IVC17
	Needleless safety closed type with dual port	IVC18

Indications for Use Statement:

Disposable IV catheter is intended to be inserted into a Patient's peripheral vascular system for short term use to sample blood, monitor blood pressure, or administer fluids. These devices may be used for any patient population with consideration given to adequacy of vascular anatomy, procedure being performed, fluids being infused, and duration of therapy. The 22-18 GA devices are suitable for use with power injectors set to a maximum pressure of 300 psi when access ports not suitable for use with power injectors are removed.

Substantially Equivalent (SE) Comparison

Table 1 General Comparison Table

ITEM	Proposed Device	Predicate Device K183399	Remark
Indications for Use Statement	Disposable IV catheter is intended to be inserted into a Patient's peripheral vascular system for short term use to sample blood, monitor blood pressure, or administer fluids. These devices may be used for any patient population with consideration given to adequacy of vascular anatomy, procedure being performed, fluids being infused, and duration of therapy. The 22-18 GA devices are suitable for use with power injectors set to a maximum pressure of 300 psi when access ports not suitable for use with power injectors are removed.	BD Nexiva closed IV catheter systems are intended to be inserted into a Patient's peripheral vascular system for short term use to sample blood, monitor blood pressure, or administer fluids. These devices may be used for any patient population with consideration given to adequacy of vascular anatomy, procedure being performed, fluids being infused, and duration of therapy. The 22-18 GA (0.9-1.3 mm) devices are suitable for use with power injectors set to a maximum pressure of 300 psi (2068 kPa) when access ports not suitable for use with power injectors are removed.	SAME
Classification	21CFR § 880.5200 Class II FOZ -Catheter, intravascular, therapeutic, short-term less than 30 days	21CFR § 880.5200 Class II FOZ -Catheter, intravascular, therapeutic, short-term less than 30 days (primary)	SAME
gauge sizes	14G,16G,18G,20G, 22G, 24G,26G	18G, 20G, 22G, 24G,	Analysis
Use with Power Injectors	Yes(18G, 20G, 22G)	Yes(18G, 20G, 22G)	SAME
Flashback visualization	Yes	Yes	SAME
Packaging	Blister	Blister	SAME
Single Sterile Wrapped	Yes	Yes	SAME
Sterilization	Ethylene oxide	Ethylene oxide	SAME

Analysis

The proposed device is different than the predicate device in Gauge Size, the proposed device has more specification of gauge size available than predicate device (14G, 16G, 26G). The difference gauge sizes is used for different clinical situations and for more choices to the physician. We have conducted bench testing to each gauge size, and the tests results meet the requirements of the recognized standards. This difference does not raise concerns of safety and effectiveness.

Table 2 Device Materials Comparison Table

ITEM	Proposed Device	Predicate Device K183399	Remark
Needle	Stainless Steel	Stainless Steel	SAME
Catheter	Polyurethane	Polyurethane	SAME
Catheter hub wings	TPE/PP	TPE	Analysis
Pinch Clam	Polyoxymethylene	Acetal	Analysis
Extension Tubing	PVC/Polyurethane	Polyurethane	Analysis
Luer Adapter	Copolyester	Copolyester	SAME

Needleless connector	Polycarbonate/ Silicone elastomer	Polycarbonate/ Silicone（Q-Syte/ MaxZero）	SAME
Heparin plug body	Copolyester	N/A	Analysis
Heparin plug Injection Port	Polyisoprene rubber(Rubber pad)	N/A	Analysis

Analysis

The proposed device and the predicate device have different materials used for the Catheter hub wings, Pinch Clam, Extension tubing, heparin plug body and heparin plug. This difference may cause a biological risk. We have conducted biological evaluation and testing with the final device, which included whole materials of proposed device, and the results shown that there is no biological risk. This difference does not raise concerns of safety and effectiveness than the predicate device.

Table 3 Primary Device Components Comparison Table

ITEM	Proposed Device		Predicate Device K183399	Remark
Needlestick injury prevention feature	Safety Straight IV Catheter System	Yes	NA	Analysis
	Safety Closed IV Catheter System			
	Needleless Safety Closed IV Catheter System			
	Straight IV Catheter System	NA	NA	SAME
	Closed IV Catheter System			
	Needleless Closed IV Catheter System			
Extension tubing（closed）	Straight IV Catheter System	NA	Yes	Analysis
	Safety Straight IV Catheter System			
	Closed IV Catheter System	Yes	Yes	SAME
	Safety Closed IV Catheter System			
	Needleless Closed IV Catheter System			
	Needleless Safety Closed IV Catheter System			
Port	Safety closed type with single port	Single port	Single Port with MaxZero	SAME
	Needleless closed type with single port			
	Needleless safety closed type with dual port	Dual Port	Dual Port with Q-Syte	SAME
	Safety closed type with dual port for Heparin plug and Needleless connector			
	Needleless closed type with dual port			
	Safety closed type with dual port for two Heparin plug	Y Connection (dual port) with two PRN adapters	Y Connection (dual port) with two PRN adapters	SAME
	Closed type with dual port			
	Safety closed type with single port	Single port	Single port	SAME
	Closed type with single port			
	Type with wings but without injection port	Single port	Single port	SAME
	Type without wings and injection port	Single port	Single port	SAME
	Type with wings and injection port	Single port + Injection Port	Single port	Analysis
	Pen type	Single port	Single port	SAME
	Safety type with wings but without	Single port	Single port	SAME

	injection port			
	Safety type without wings and injection port	Single port	Single port	SAME
	Safety type with wings and injection port	Single port + Injection Port	Single port	Analysis
	Safety pen type	Single port	Single port	SAME
	Safety anti-reflux type	Single port + Injection Port	Single port	Analysis

Analysis

The proposed device has a slightly different passive Needlestick injury prevention feature than the predicate device. We have conducted bench testing per ISO 23908 and the tests results meet the requirements of the recognized standards. This difference does not raise concerns of safety and effectiveness.

The proposed device is different than the predicate device in that it is available with and without Extension tubing, it will not affect the normal use of the product and does not change the intended use. Testing has been conducted in accordance with ISO 10555-1:2013, and the test results meet the standard requirements, so this difference does not raise concerns of safety and effectiveness.

The proposed device has an Injection Port, the predicate device does not have Injection port, this port is used for dosing during infusion, it will provide more choices to the physician for different clinical situations. We have conducted bench tests to this port (ISO 10555-1, Leakage Test). This difference does not raise concerns of safety and effectiveness.

Table 4 Performance Comparison Table

ITEM	Proposed Device	Predicate Device K183399	Remark
Bio	Accordance with ISO 10993 -1:2009 and referencing FDA guidance entitled "Use of International Standard ISO 10993- 1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".	Accordance with ISO 10993 -1:2009 and referencing FDA guidance entitled "Use of International Standard ISO 10993- 1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".	SAME
Power injection test	Catheter burst pressure exceeds the peak pressure present in the catheter at maximum flow conditions when tested according to ISO 10555-1:2013	No detail test information	Analysis
Flow rate test	The flow rate through catheter meets allowable limits when tested according to ISO 10555-1:2013	No detail test information	Analysis
Vent fitting test for the needle hub	The needle hub with the packing part is impervious to liquid infiltration when subjected to positive pressure in accordance with ISO 10555 - 5: 2013.	No detail test information	Analysis
Ease of assembly performance testing for the plunger	The plunger passes through the check valve when tested according to ISO 594-2:1998	No detail test information	Analysis

Analysis

Information about testing of predicate device performance is not available, so these tests are considered as different. We have conducted bench tests (ISO 10555-1, ISO 10555-5, ISO 594-2), and the tests results meet the requirements of the recognized standards. These differences do not raise concerns of safety and effectiveness.

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 9626:2016: Stainless steel needle tubing for the manufacture of medical devices. Requirements and test methods
- ISO 10555-1: 2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements
- ISO 10555-5: 2013 Intravascular catheters - Sterile and single-use catheters - Part 5: Over-needle peripheral catheters
- ISO23908：2011 Sharps injury protection - Requirements and test methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling.
- ISO 80369-7: 2016 Small-bore connectors for liquids and gases in healthcare applications - Part 7 : Connectors for intravascular or hypodermic applications
- ASTM F1980-07 Standard guide for accelerated aging of sterile barrier systems for medical device.
- ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity
- ISO 10993-4:2017 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 10993-6:2016 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation
- ISO 10993-7:2009 Biological Evaluation of Medical Device – Part 7: Ethylene Oxide Sterilization residuals.
- ISO 10993-10:2010 Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization.
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Clinical Test Conclusion

No clinical study is included in this submission.

Substantially Equivalent (SE) Conclusion

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