May 18, 2023

BQ PLUS Medical Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120
China

Re: K223645
Trade/Device Name: I.V. Administration Set, I.V. Extension Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: April 17, 2023
Received: April 17, 2023

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,

Porsche Bennett

Porsche Bennett
For David Wolloscheck
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)*
K223645

Device Name
I.V. Administration Set, I.V. Extension Set

Indications for Use *(Describe)*
The I.V. Administration Set intended use is to deliver sterile, infusion fluid from a container to the patient with or without flow control features.
The I.V. Extension Set may act as an extension of other infusion tubing in delivering intravenous fluids from a container to patient.

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.

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K223645- 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: K223645

1. Date of Preparation: 05/18/2023

2. Sponsor Identification

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3. Designated Submission Correspondent

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4. Identification of Subject Device and Predicate Device

Trade Name: I.V. Administration Set, I.V. Extension Set
Common Name: Intravascular Administration Set

Regulatory Information
Classification Name: Set, Administration, Intravascular
Classification: II
Product Code: FPA
Regulation Number: 21 CFR 880.5440
Review Panel: General Hospital

Predicate Device
510(k) Number: K111351
Product Name: TRUECARE BIOMEDIX INTRAVASCULAR ADMINISTRATION SET, TRUECARE BIOMEDIX EXTENSION SET

Indications for Use:

The I.V. Administration Set intended use is to deliver sterile, infusion fluid from a container to the patient with or without flow control features.
The I.V. Extension Set may act as an extension of other infusion tubing in delivering intravenous fluids from a container to patient.

Device Description:

The subject device is a single use device. It has ten models. The models and their features are listed in Table 1. The ten models have differences in configurations. The differences are provided in Table 2.

Table 1 Description of Models

Model	Feature
BQAS-0201	I.V. Administration Set with Clamp, Back Check Valve
BQAS-0202	I.V. Administration Set with Clamp
BQAS-0203	I.V. Administration Set with Flow Regulator, 15um Filter
BQAS-1201	I.V. Administration Set with Back Check Valve
BQAS-1202	I.V. Administration Set with Clamp
BQAS-1203	I.V. Administration Set with Flow Regulator, 15um Filter
BQES-MF01	I.V. Extension Set with Female Lure Connector
BQES-MF02	I.V. Extension Set with Female Lure Connector

BQES-MF03	I.V. Extension Set with Needle free Type Y
BQES-MF04	I.V. Extension Set with Needle free Type Y

The I.V. Administration Set is used to deliver sterile, infusion fluid from a container to the patient with or without flow control features. The I.V. Extension Set may act as an extension of other infusion tubing in delivering intravenous fluids from a container to patient.

There are ten different models, each configuration containing various components which may include: Spike Protector, Vented Air Cap, Air Filter, Spike, Drip Chamber, 10 Drops, Tubing, Back Check Valve, Needle Free TYPE Y, Clamp, Roller Clamp, Roller, Precision Filter, Robert Clamp, Male Luer Slip, Luer Lock Ring, Protective Cap, 15um Filter, Flow Regulator, Female Luer Connector. The devices are provided sterile and single use.

Table 2 Configuration of I.V. Administration Set

Configuration	BQAS-0201	BQAS-0202	BQAS-0203	BQAS-1201	BQAS-1202	BQAS-1203	BQES-MF01	BQES-MF02	BQES-MF03	BQES-MF04
Spike Protector	X	X	X	X	X	X			X	X
Vented Air Cap	X	X	X	X	X	X			X	X
Air Filter	X	X	X	X	X	X			X	X
Spike	X	X	X	X	X	X			X	X
Drip Chamber	X	X	X	X	X	X				
10 Drops	X	X		X	X					
Tubing	X	X	X	X	X	X	X	X	X	X
Back Check Valve	X			X						
Needle Free TYPE Y	X	X	X	X	X	X			X	X
Clamp	X	X		X	X					
Roller Clamp	X	X	X	X	X	X				
Roller	X	X	X	X	X	X				
Precision Filter	X	X	X	X	X	X	X	X	X	X
Robert Clamp	X	X	X	X	X	X	X	X	X	X
Male Luer Slip	X	X	X	X	X	X	X	X	X	X
Luer Lock Ring	X	X	X	X	X	X	X	X	X	X
Protective Cap	X	X	X	X	X	X			X	X
15um Filter			X			X				
Flow Regulator			X			X				
Female Luer Connector							X	X		
Female Luer Cap							X	X		

The description for each component is provided as follows:

Component	Function
Spike Protector	The spike protector is used to protect the piercing device to prevent stab wounds
Vented Air Cap	When the plastic needle is punctured, the cap should be tightly covered to prevent liquid from flowing out
Air Filter	It is used to filter air.
Spike	The spike is used to puncture the infusion bottle (or infusion bag).
Drip Chamber	The drip chamber is used to observe the liquid level.
10 Drops	The 10 drops is used to calculate the drop rate.
Tubing	The tubing is intended to deliver fluid.
Back Check Valve	The back check valve is intended to prevent the liquid backflow.
Needle Free TYPE Y	It is used to add medicine with syringes without needle
Clamp	The clamp is intended to stop the fluid flowing.
Roller Clamp	Adjust the fluid flow
Roller	Adjust the fluid flow
Precision Filter	Filter particulate matter in liquid medicine
Robert Clamp	The robert clamp is intended to stop the fluid flowing.
Male Luer Slip	For connection between pipes (or with patient end)
Luer Lock Ring	For connection between pipes (or with patient end)
Protective Cap	The protection of the Luer connector and the exhaust of the pipeline
15um Filter	Used to filter particulate matter in liquid medicine.
Flow Regulator	The flow regulator is intended to adjust the liquid flow.
Female Luer Connector	The female luer connector is intended to connect the injection accessories.

The subject devices are sterilized by EO to achieve a SAL 10^{-6} and supplied in sterility maintenance package which could maintain the sterility of the device during the shelf life of 3 years.

5. Summary of Technological characteristics

Table 3 Comparison for Technology Characteristics of I.V. Administration Set

Item	Subject Device	Predicate Device K111351	Remark
Product Code	FPA	FPA	Same
Regulation No.	21 CFR 880.5440	21 CFR 880.5440	Same
Class	II	II	Same
Indication for Use	The I.V. Administration Set intended use is to deliver sterile, infusion fluid from a container to the patient with or without flow control features. The I.V. Extension Set may act as an extension of other infusion tubing in delivering intravenous fluids from a container to patient.	Truecare Biomedix Intravascular administration set intended use is to deliver sterile, infusion fluid from a container to the patient with or without flow control features. Truecare Biomedix infusion tubing may act as an extension of other infusion tubing in delivering intravenous fluids from a container to patient.	Same
Configuration	Spike Protector Vented Air Cap Air Filter Spike Drip Chamber 10 Drops Tubing Back Check Valve Needle Free TYPE Y Clamp Roller Clamp Roller Precision Filter Robert Clamp Male Luer Slip Luer Lock Ring Protective Cap 15um Filter Flow Regulator	Universal spike Drip Chamber Tubing Flow Regulator Roller clamp Slide Clamp Luer Locks Filters Y-injection site	Analysis 1
Operation Mode	Manual	Manual	Same
Label/Labeling	Conform with 21 CFR Part 801	Conform with 21 CFR Part 801	Same

Item	Subject Device		Predicate Device K111351	Remark
Infusion Set Performance	Conform with ISO 8536-4		Conform with ISO 8536-4	Same
Flow Rate of Flow Regulator(ml/h)	20 to 250		5 to 250	Analysis 2
Filter Characteristics	0.2μm, 1.2μm		0.2μm, 1.2μm	Same
Patient-contact Material				
Vented Air Cap	PVC		Acrylonitrile Butadiene Styrene Non-DEHP Poly Vinyl Chloride Polypropylene Silicone	Analysis 3
Air Filter	PTFE			
Spike	ABS			
Drip Chamber	PVC			
10 Drops	ABS			
Tubing	PVC			
Back Check Valve	MABS			
Needle Free TYPE Y	MABS, PP, Silicone			
Precision Filter	PTFE, PES, MABS			
Male Luer Slip	PC			
Luer Lock Ring	PC			
Protective Cap	PP			
15um Filter	ABS, Nylon			
Flow Regulator	ABS,TPE			
Physical specifications				
Connection Type	Luer Connection		Luer Connection	Same
Priming Volume	15.04±2ml~17.85±2ml		Unknown	Analysis 4
Total Length	2320±100~2580±100mm		127~2667mm (5”~105”)	Analysis 5
Color of component	Vented Air Cap	Blue	Unknown	Analysis 6
	Air Filter	White		
	Spike	White		
	10 Drops	White		
	Back Check Valve	White		
	Needle Free TYPE Y	Blue		
	Protective Cap	Blue		
	15um Filter	White		

Item	Subject Device		Predicate Device K111351	Remark
	Flow Regulator	White		
Sterilization				
Method	EO sterilized		EO sterilized	Same
SAL	10^{-6}		10^{-6}	Same

Analysis 1-Configuration

The predicate device components are a subset of the subject device components. The common components between the subject and predicate devices names are different, but the components functionality are the same. The common components and additional components of the subject device have been adequately tested for performance, biocompatibility and sterility. The differences do not raise new questions of safety and effectiveness.

Analysis 2- Flow Rate of Flow Regulator

The flow rate for subject device is different from predicate device. However, the flow rate range of the subject device is within the flow rate range of the predicate device. The subject device was tested according to the standard of ISO 8536-14:2016, and the test results demonstrate that the flow regulator can meet its intended flow rate requirements. Thus, the difference does not raise new questions of safety and effectiveness.

Analysis 3- Patient-contact Material

The patient contact materials for the subject device are different from the predicate device. However, biocompatibility testing has been conducted on the subject device in accordance to ISO 10993-1. Thus, the differences do not raise new questions of safety and effectiveness.

Analysis 4-Priming Volume

The priming volume for the subject device is different from the predicate device. The priming volume depends on the length of the device, so the priming volume of the subject device and predicate device is different. However, the indications for use and functionality of the devices are the same; therefore, the differences do not raise new questions of safety and effectiveness.

Analysis 5-Total Length

The total length for the subject device is different from the predicate device. However, the length of the subject device is within the specification limits of the length of the predicate device. The subject device was tested according to ISO 8536-4:2019, and the test results for subject device demonstrate that the length can meet its specified dimensional requirements. Thus, the differences do not raise new questions of safety and effectiveness.

Analysis 6-Color of Component

The color of the component of the predicate device is unknown; however, biocompatibility testing has been

conducted on the subject device demonstrating safety. Thus, the differences do not raise new questions of safety and effectiveness.

Table 4 Comparison for Technology Characteristics of I.V. Extension Set

Item	**Subject Device**	**Predicate Device K111351**	**Remark**
Product Code	FPA	FPA	Same
Regulation No.	21 CFR 880.5440	21 CFR 880.5440	Same
Class	II	II	Same
Indication for Use	The I.V. Administration Set intended use is to deliver sterile, infusion fluid from a container to the patient with or without flow control features. The I.V. Extension Set may act as an extension of other infusion tubing in delivering intravenous fluids from a container to patient.	Truecare Biomedix Intravascular administration set intended use is to deliver sterile, infusion fluid from a container to the patient with or without flow control features. Truecare Biomedix infusion tubing may act as an extension of other infusion tubing in delivering intravenous fluids from a container to patient.	Same
Configuration	Spike Protector Vented Air Cap Air Filter Spike Tubing Needle Free TYPE Y Precision Filter Robert Clamp Male Luer Slip Luer Lock Ring Protective Cap Female Luer Connector Female Luer Cap	Universal spike Drip Chamber Tubing Flow Regulator Roller clamp Slide Clamp Luer Locks Filters Y-injection site	Analysis 7
Operation Mode	Manual	Manual	
Label/Labeling	Conform with 21 CFR Part 801	Conform with 21 CFR Part 801	Same
Infusion Set Performance	Conform with ISO 8536-4	Conform with ISO 8536-4	Same
Patient-contact Material			
Vented Air Cap	PVC	Acrylonitrile Butadiene Styrene	Analysis 8

Air Filter	PTFE		Non-DEHP Poly Vinyl Chloride Polypropylene Silicone	
Spike	ABS			
Tubing	PVC			
Needle Free TYPE Y	MABS, PP, Silicone			
Precision Filter	PTFE, PES, MABS			
Male Luer Slip	PC			
Luer Lock Ring	PC			
Protective Cap	PP			
Female Luer Connector	PC			
Filter Characteristics	0.2μm, 1.2μm		0.2μm, 1.2μm	Same
Physical specifications				
Connection Type	Luer Connection		Luer Connection	Same
Priming Volume	4.24±0.5ml~4.32±0.5ml		unknown	Analysis 9
Total Length	435±15mm~460±15mm		177mm (5inch)	Analysis 10
Color of component	Vented Air Cap	Blue	Unknown	Analysis 11
	Air Filter	White		
	Spike	White		
	10 Drops	White		
	Back Check Valve	White		
	Needle Free TYPE Y	Blue		
	Protective Cap	Blue		
	15um Filter	White		
	Flow Regulator	White		
Sterilization				
Method	EO sterilized		EO sterilized	Same
SAL	10^{-6}		10^{-6}	Same

Analysis 7-Configuration

The predicate device components are a subset of the subject device components. The common components between the subject and predicate devices names are different, but the components functionality are the same. The common components and additional components of the subject device have been adequately tested for performance, biocompatibility and sterility. The differences do not raise new questions of safety and effectiveness.

Analysis 8- Patient-contact Material

The patient contact materials for the subject device are different from the predicate device. However, biocompatibility testing has been conducted on the subject device in accordance to ISO 10993-1. Thus, the differences do not raise new questions of safety and effectiveness.

Analysis 9-Priming Volume

The priming volume for the subject device is different from the predicate device. The priming volume depends on the length of the device, so the priming volume of the subject device and predicate device is different. However, the indications for use and functionality of the devices are the same; therefore, the differences do not raise new questions of safety and effectiveness.

Analysis 10-Total Length

The total length for subject device is different from predicate device. However, different lengths can be used for different patients and clinical conditions. The subject device was tested according to ISO 8536-4:2019, and the test result for subject device show that the length can meet its specified dimensional requirements. Thus, the differences do not raise new questions of safety and effectiveness.

Analysis 11-Color of Component

The color of the component of the predicate device is unknown; however, biocompatibility testing has been conducted on the subject device demonstrating safety. Thus, the differences do not raise new questions of safety and effectiveness.

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the subject device complies with the following complete standards：

Performance

- ISO 8536-4:2019 Infusion equipment for medical use, Part 4: Infusion sets for single use, gravity feed
- ISO 8536-12:2007 AMD 1 2012 Infusion equipment for medical use- Part 12: Check valves
- ISO 8536-14:2016 Infusion equipment for medical use - Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact
- ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications —Part 7: Connectors for intravascular or hypodermic applications
- ASTM F838-15a Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration
- USP<788> Particulate matter in injections

Biocompatibility

The subject device contact classification is an externally communicating device, blood path indirect, prolonged exposure.

- 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 10993-10: 2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization;
- ISO10993-11: 2017, Biological evaluation of medical devices—Part 11: Tests for Systemic Toxicity
- USP <151> Pyrogen Test

Sterilization

- ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation, and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]
- ASTM F88/F88M-15: Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F756-17 Standard practice for assessment of hemolytic properties of materials
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- USP <85> Bacterial Endotoxins Test
- Microbial Ingress Testing
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers

7. Summary of Clinical Testing

No clinical study is included in this submission.

8. Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The subject device, I.V. Administration Set, I.V. Extension Set is substantially equivalent to the predicate device, TRUECARE BIOMEDIX INTRAVASCULAR ADMINISTRATION SET, TRUECARE BIOMEDIX EXTENSION SET cleared under K111351.