August 14, 2021

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

Re: K210381
Trade/Device Name: I.V. Administration Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: June 28, 2021
Received: July 15, 2021

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,

Payal Patel
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)*
K210381

Device Name
I.V. Administration 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary K210381

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K210381

1. Date of Preparation: 06/28/2021

2. Sponsor Identification

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Establishment Registration Number: Not yet registered.

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

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

Regulatory Information
Classification Name: Set, Administration, Intravascular
Classification: II
Product Code: FPA
Regulation Number: CFR 880. 5440

Review Panel: General Hospital

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 propose device, I.V. Administration Set, is a single used device. It has seven models. The models and their features are listed in Table 1.

Table 1 Description of Models

Model	Feature
BQ-SYQ-001	I.V. Administration Set with T connector, Y site, flow regulator, Needle Free Valve
BQ-SYQ-002	I.V. Administration Set with Hanger
BQ-SYQ-003	I.V. Administration Set with Y site, Needle free Valve
BQ-SYQ-004	I.V. Administration Set with Flow Regulator
BQ-YCG-017	I.V. Extension Set with T connector, Needle Free Valve
BQ-YCG-018	I.V. Extension Set with Needle Free Valve
BQ-YCG-019	I.V. Extension Set with male/female luer lock

There are seven different models, each configuration comprise of various components which may include: IV Chamber, Tubing, Roller Clamp, Y Site, Needle Free Valve, Slide Clamp, Back Check Valve, Male Luer Lock, 3 Way Stop Cock, Female Luer Lock, Flow Regulator, Rotating Luer Lock, T-Connector, Luer Lock Cap, Hanger, Drop, Female Luer Connector and Cap. The devices are provided sterile and single use.

The proposed 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. Identification of Predicate Devices

510(k) Number: K121803
Product Name: Acta Medical Intravascular Administration Set

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was same/similar to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- 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
- 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
- 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 43-NF 38 <85> Bacterial Endotoxins Test
- USP 43-NF 38 <151> Pyrogen Test

Biocompatibility Testing

The contact level of the proposed device is blood path, indirect and the contact duration is prolonged duration. The proposed device was evaluated for the following tests. The results of the biocompatibility testing showed that there are no negative impacts from the materials that are used in the proposed device.

- Hemolysis Test Report
- Cytotoxicity Test Report
- Guinea Pig Maximization Test Report
- Intracutaneous Reactivity Test Report

- Systemic Toxicity Test Report
- Pyrogen Test Report

Performance Testing-Bench

- Particulate contamination, leakage, tensile strength, dimension of the closure-piercing device, determination of flow rate when using an air-inlet device, tubing, efficiency of the fluid filter, drip chamber and drip tube, Flow rate of infusion fluid and injection site Performance Test Report of ISO 8536-4
- Check valves Performance Test Report of ISO 8536-12
- Flow regulator Performance Test Report of ISO 8536-14
- Luer Compliance Performance Test Report of ISO 80369-7

Performance Testing-Microbial Ingress Test

- Microbial Ingress Testing

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technological Characteristics

Table 1 Comparison of Technology Characteristics

ITEM	**Proposed Device** I.V. Administration Set	**Predicate Device** K121803	**Remark**
Regulation Number	CFR 880.5440	CFR 880.5440	Same
Product Code	FPA	FPA	Same
Class	II	II	Same
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.	Acta Medical Intravascular administration set intended use is to deliver sterile, infusion fluid from a container to the patient with or without flow control features. Acta Medical infusion tubing may act as an extension of other infusion tubing in delivering intravenous fluids from a container to patient.	Same
Configuration of I.V. Administration Set	IV Chamber, Tubing, Roller Clamp, Y Site,	Protector Cap of Spike Spike Air Vent Air Filter	Different 1

	Needle Free Valve, Slide Clamp, Back Check Valve, Male Luer Lock, 3 Way Stop Cock, Female Luer Lock, Flow Regulator, Rotating Luer Lock, T-Connector, Luer Lock Cap, Hanger, Drop	Drip Chamber Fluid Filter Flexible Tube Flow Regulator Check Valve Needle Free Y Injection Site Roller Clamp Y Injection Site Precision Filter Pinch Clamp Luer Lock Connector Protector Cap of Luer Lock Connector	
Configuration of I.V. Extension Set	Tubing, Needle Free Valve, Slide Clamp, Male Luer Lock, Female Luer Lock, Rotating Luer Lock, T-Connector, Luer Lock Cap, Female Luer Connector, Cap	Tubing, Needle Free Valve, Slide Clamp, Male Luer Lock, Female Luer Lock, Rotating Luer Lock, T-Connector, Luer Lock Cap, Female Luer Connector, Cap	Same
Operation Mode	Manual	Manual	Same
Label/Labeling	Conform with 21 CFR Part 801	Conform with 21 CFR Part 801	Same
Infusion Set Performance	Conform with ISO 8536-4:2010 and ISO 8536-12: 2004	Conform with ISO 8536-4:2010 and ISO 8536-12: 2004	Same
Flow Rate of Flow Regulator (ml/h)	20 to 250	5 to 250	Different 2
Pore Size of Membrane	15μm	0.2μm, 1.2μm, 15μm	Different 3
Patient- contact Material			
IV Chamber	ABS, PVC	Acrylonitrile Butadiene Styrene	Different 4
Tubing	PVC		
Y Site	PC	Non-DEHP Poly Vinyl Chloride	
Needle Free Valve	ABS, PP, Silicone		
Back Check Valve	ABS,TPE	Polypropylene (non fluid pathway material, utilized in protective caps only)	
Male Luer Lock	ABS		
3 Way Stop Cock	PC, PP, POM		
Female Luer Lock	PC		
Flow Regulator	ABS, TPE	Silicone	

Rotating Luer Lock	PC		
T-Connector	PC		
Luer Lock Cap	PP		
Drop	ABS		
Female Luer Connector	PC		
Cap	ABS		
Biocompatibility			
Cytotoxicity	No cytotoxicity.	The specific test items are unknown. However, the product should meet the requirements of ISO10993 series standards.	Different 5
Max Sensitization	No skin sensitization.		
Intracutaneous Reactivity Test	No intracutaneous reactivity.		
Acute Systemic Toxicity Test	No systemic toxicity.		
Pyrogen Test	No potential febrile reaction.		
Hemolysis Test	No Hemolysis		
Sterilization			
Method	EO Sterilized	EO Sterilized	Same
SAL	1.0×10^{-6}	1.0×10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same
Single Use	Yes	Yes	Same

Different 1 – Configuration

The configuration for proposed device is different from predicate device. The components of proposed device are same with the components of predicate device. Only the component name is different. Thus, this difference does not affect the safety and effectiveness of the proposed device.

Different 2- Flow Rate

The flow rate for proposed device is different from predicate device. However, the flow rate range of the proposed device is within the flow rate rang of the predicate device. And the test result for proposed device show that flow regulator can meet its declared flow rate requirements. Thus, this difference does not affect the safety and effectiveness of the proposed device.

Different 3- Pore Size of Membrane

The pore size of membrane for proposed device is different from predicate device. However, the pore size of membrane for proposed device is within the pore size of membrane for predicate device. And the test result for proposed device shows that the retention of latex particles on the filter can meet its declared pore size of membrane. Thus, this difference does not affect the safety and effectiveness of the proposed device.

Different 4- Patient- contact Material

The patient contact materials for proposed device are different from predicate device. However, the biocompatibility test for proposed device was performed and the result show there is no adverse effect. Thus, this difference does not affect the safety and effectiveness of the proposed device.

Different 5- Biocompatibility

The biocompatibility of Proposed Device and Predicate Device are should meet the requirements of ISO10993 series standards; although we do not know the specific test items of Predicate Device, but the biocompatibility tests of Proposed Device have been performed in Cytotoxicity, Max Sensitization, Intracutaneous Reactivity Test, Acute Systemic Toxicity Test, Pyrogen Test and Hemolysis Test. These studies can demonstrate the biocompatibility of Proposed Device. Thus, this difference does not affect the safety and effectiveness of the proposed device.

9. Conclusion

Through performance testing the subject device has demonstrated substantial equivalence to the predicate device.