February 26, 2019

Wuhan W.E.O Science & Technology Development Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K181870
Trade/Device Name: Infusion Sets with Precision Filter for Single Use, Precision Infusion Filter for Single Use, Extended Infusion Sets for Single Use
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA, FPB
Dated: January 9, 2019
Received: January 23, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sapana Patel -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K181870

Device Name
Infusion Sets with Precision Filter for Single Use
Precision Infusion Filter for Single Use
Extended Infusion sets for Single Use

Indications for Use *(Describe)*
The Infusion Sets with Precision Filter for Single Use is indicated for the delivery of fluids from a container to a patient's vascular system for short term infusions only.

The Precision Infusion Filter for Single Use is intended to be used with administration sets or extension sets for removal of particulate matter during the administration of fluids or medications.

The Extended Infusion Sets for Single Use is intended to be used in I.V. therapy when an extended fluid path is requirement for administration.

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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510(K) Summary K181870

Manufacturer's Name:
Wuhan W.E.O Science & Technology Development Co., Ltd.
No.18, Huanhu Mid. Rd., Jinyin Lake, Dongxihu Dist., 430040 Wuhan, People's Republic of China

Name of Corresponding Official:
Diana Hong
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119, Shanghai, 200120, China

Telephone Number: +86-21-22815850
Fax Number: 360-925-3199

Summary Date: 02/22/2019

Trade Name: Infusion Sets with Precision Filter for Single Use
Precision Infusion Filter for Single Use
Extended Infusion Sets for Single Use

Common Name: I.V. Administration Set
Infusion Line Filter

Regulation Name: Intravascular Administration Set

Regulation Number: 21 CFR 880.5440

Product Code: FPA (IV Administration Set, Extended Infusion Sets for Single Use)
FPB (Infusion Line Filter)

Predicate Devices:

Infusion Sets with Precision Filter for Single Use
Predicate Device 510(K) Number: K161898
Product Name: Burette-type Infusion Sets for Single Use, Disposable Infusion Sets with Precision Filters, Disposable Infusion Set

Precision Infusion Filter for Single Use Predicate
Device 510(K) Number: K974661 Product Name:
0.2µ bacterial filter

Extended Infusion Sets for Single Use
Predicate Device 510(K) Number: K061115
Product Name: SPEEDFLOW 0.2UM FILTER, MODEL 11214; SPEEDFLOW 1.2UM FILTER, MODEL 11215; EASYDROP CONTROLLER, MODEL 11216

Device Description:

The purpose of this submission was to introduce new products into interstate commerce. This is a bundled submission which includes Infusion Sets with Precision Filter for Single Use, Precision Infusion Filter for Single Use and Extended Infusion Sets for Single Use.

Infusion Sets with Precision Filter for Single Use:
Infusion Sets with Precision Filter for Single Use is indicated for the delivery of fluids from a container to a patient's vascular system under the action of gravity. The proposed devices are comprised of protective cap, closure-piercing device, air vent, drip chamber, precision filter, flexible tubing, injection site, flow regulator, clamp, conical fitting, burette and needle tube. The devices are provided sterile and single use.

Precision Infusion Filter for Single Use:
Precision Infusion Filter for Single Use is intended to be used with administration sets or extension sets for removal of particulate matter during the administration of fluids or medications. The proposed devices are comprised of protective Cap and precision filter. The devices are provided sterile and single use.

Extended Infusion Sets for Single Use:
Extended Infusion Sets for Single Use is intended to be used in I.V. therapy when an extended fluid path is requirement for administration. The proposed devices are comprised of protective Cap, flexible tubing, conical fitting and precision filter. The devices are provided sterile and single use.

Indications for Use:

The Infusion Sets with Precision Filter for Single Use is indicated for the delivery of fluids from a container to a patient's vascular system for short term infusions only.

The Precision Infusion Filter for Single Use is intended to be used with administration sets or extension sets for removal of particulate matter during the administration of fluids or medications.

The Extended Infusion Sets for Single Use is intended to be used in I.V. therapy when an extended fluid path is requirement for administration.

Comparison for Infusion Sets with Precision Filter for Single Use

ITEM	Proposed Device	Predicate Device 1 K161898	Discussion
Regulation No.	21 CFR 880.5440	21 CFR 880.5440	Same
Product Code	FPA	FPA	Same
Class	II	II	Same
Indication for Use	The Infusion Sets with Precision Filter for Single Use is indicated for the delivery of fluids from a container to a patient's vascular system for short term infusions only.	The devices are indicated for the delivery of fluids from a container to a patient's vascular system.	Discussion 1
Configuration	Protector Cap of Closure-piercing Device Closure-piercing Device Air Vent Burette Air Filter Drip Chamber Precision Filter Flexible Tubing Flow Regulator Y Injection Site Clamp Conical Fitting Protective Cap of Conical Fitting Needle Tube	Protector Cap of Closure-piercing Device Closure-piercing Device Air Vent Burette Air Filter Drip Chamber Precision Filter Flexible Tubing Flow Regulator Y Injection Site Clamp Conical Fitting Protective Cap of Conical Fitting Needle Tube	Same
Material	PP, ABS, PVC, PE, Stainless Steel, Acrylonitrile-styrene	PC, ABS, PVC, PE, POM, Acrylonitrile-styrene, Stainless Steel,	Discussion 2
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 and ISO 8536-5	Conform with ISO 8536-4 and ISO 8536-5	Same
Needle Performance	Conform with ISO 7864 and ISO 9626	Conform with ISO 7864 and ISO 9626	Same
Needle gauge and	22G×25mm	22G×20mm	Discussion 3
Sterilization			
Method	EO sterilized	EO sterilized	Same
SAL	10^{-6}	10^{-6}	
Biocompatibility			
Cytotoxicity	No cytotoxicity	Comply with ISO 10993	Same
Intracutaneous reactivity	No Intracutaneous reactivity		
Skin Sensitization	No Skin Sensitization		
Acute Systematic Toxicity	No Acute Systematic Toxicity		
Hemolysis	No Hemolysis		
Pyrogen	No Pyrogen		
Complement activation	No complement activation		
Thrombosis Test	No thrombosis		

Discussion 1
The indication of short term infusion is not included in predicate device. However, the predicate device is same as the proposed device and also indicated for short term infusion rather than long term infusion, therefore, this difference does not affect substantially equivalence.

Discussion 2
The material for proposed device is different from predicate device. However, the biocompatibility test for proposed device has been conducted and the test result conform with requirements of ISO 10993 standards. Therefore, this difference does not affect substantially equivalence.

Discussion 3
The needle length for proposed device is different from predicate device. However, this difference is just in dimension. Different length will be selected by physician per patient's condition. This difference does not affect intended use. Therefore, this difference does not affect substantially equivalence.

Comparison for Precision Infusion Filter for Single Use

ITEM	Proposed Device	Predicate Device 2	Discussion
Regulation No.	21 CFR 880.5440	21 CFR 880.5440	Same
Product Code	FPB	FPB	Same
Class	II	II	Same
Intended Use	The Precision Infusion Filter for Single Use is intended to be used with administration sets or extension sets for removal of particulate matter during the administration of fluids or medications.	The 0.2μ bacterial filter can be used with administration sets or extension sets for removal of particulate matter during the administration of fluids or medications.	Same
Configuration	Protective Cap Precision Filter	Protectiv e Cap	Same
Material	PP, Acrylonitrile-styrene	Unknown	Discussion 4
Operation Mode	Manual	Manual	Same
Pore Size of Membrane	1.2μm, 0.2μm	0.2μm	Discussion 5
Sterilization			
Method	EO sterilized	EO sterilized	Same
SAL	10^{-6}	10^{-6}	
Endotoxin Limit	20 EU per device	20 EU per device	
Biocompatibility	Comply with ISO 10993	Comply with ISO 10993	Same

Discussion 4
The material for predicate device is unknown and substantially equivalence between proposed device and predicate device cannot be determined. However, the biocompatibility test for proposed device has been conducted and the test result conform with requirements of ISO 10993 standards. Therefore, this difference does not affect substantially equivalence.

Discussion 5
The proposed device has the additional pore size 1.2μm compared to predicate device. However, the filter performance has tested and the test result can meet the acceptance criteria. Therefore, this difference does not affect substantially equivalence.

Comparison for Extended Infusion Sets for Single Use

ITEM	Proposed Device	Predicate Device 3 K061115	Discussion
Regulation No.	21 CFR 880.5440	21 CFR 880.5440	Same
Product Code	FPA	FPA	Same
Class	II	II	Same
Intended Use	The Extended Infusion Sets for Single Use is intended to be used in I.V. therapy when an extended fluid path is requirement for administration.	Indicated as a single use, sterile device for use in I.V. therapy when an extended fluid path is requirement for administration. Environment of use: Hospital, Emergency Medical Services settings, wherever I.V. fluid administration may be indicated.	Discussion 6
Configuration	Protective Cap Precision Filter Flexible tubing Conical fitting	Protective Cap Precision Filter Flexible tubing Conical fitting	Same
Material	PP, ABS, PVC, AS	Unknown	Discussion 7
Operation Mode	Manual	Manual	Same
Pore Size of Membrane	1.2μm, 0.2μm	1.2μm, 0.2μm	Same
Sterilization			
Method	EO sterilized	EO sterilized	Same
SAL	10^{-6}	10^{-6}	
Endotoxin Limit	20 EU per device	20 EU per device	
Biocompatibility	Comply with ISO 10993	Comply with ISO 10993	Same

Discussion 6
The indication for use of proposed device does not specify the environment of use. However, the proposed device shall be also used in the environment wherever I.V. fluid administration is required. Therefore, this difference does not affect substantially equivalence.

Discussion 7
The material for predicate device is unknown. However, the biocompatibility test for proposed device has been conducted and the test result conform with requirements of ISO 10993 standards. Therefore, this difference does not affect substantially equivalence.

Clinical Testing: No clinical study is included in this submission.

Non-Clinical Test Summary

Design verification and validation were performed to ensure that the proposed devices meet its performance specifications and demonstrates equivalence to the specified predicate device. The test conducted on the proposed device are listed in following

Physical, Mechanical and Chemical Tests performed on the proposed devices include The

following items were tested on Infusion Sets with Precision Filter for Single Use:

ISO 8536-4:2010 and AMD 1 2013
ISO 8536-5: 2004
ISO 8536-14:2016
ISO 594-2:1998
ISO 7864:2016
ISO 9626:2016

The following items were tested for Precision Infusion Filter for Single Use: ISO

8536-4: 2010 and AMD 1 2013
ISO 594-2:1998

The following items were tested for Extended Infusion Sets for Single Use: ISO
8536-4:2010 and AMD 1 2013
ISO 594-2:1998

Sterile Barrier Packaging Testing performed on the all proposed devices, the test items are listed in following:

Seal strength	ASTM F88/F88-15
Dye Penetration	ASTM F 1929-15

Sterilization and Shelf Life Testing performed on the all proposed devices, the test items are listed in following:

EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Bacteria Endotoxin Limit	USP <85>
Shelf Life Evaluation	Physical, Mechanical, Chemical, Package and Sterility Tests were performed on aging samples to verify the claimed shelf life of the device.

Biocompatibility Test

Biocompatibility test was conducted on the largest size of proposed device, the test items include Cytotoxicity (ISO 10993-5), Intracutaneous reactivity (ISO 10993-10), Skin

Sensitization (ISO 10993-10), Acute Systematic Toxicity (ISO 10993-11), Hemolysis (ASTM F756), Pyrogen (USP <151>), Complement activation (ISO 10993-4) and Thrombosis (ISO 10993-4).

Conclusion:

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