June 9, 2023

Yangzhou Wei De Li Trade Co. Ltd
% Aaron Compton
President
Vesco Devices
541 Lakewood Drive
Fairview, Texas 75069

Re: K230992
Trade/Device Name: DJF Intravascular Administration Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: March 13, 2023
Received: April 11, 2023

Dear Aaron Compton:

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,

David Wolloscheck

David Wolloscheck, PhD.
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)*
K230992

Device Name
DJF Intravascular Administration Set

Indications for Use *(Describe)*
DJF Intravascular Administration Sets are intended for use with Curlin (Moog) Infusion Pump, for the delivery of fluids from a container or bag to the patient's vascular system

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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K230992- 510K Summary

Submitter Information	
Submitted By:	Yangzhou Wei De Li Trade Co. Ltd.
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Establish Registration No.	3008808123
Name of Contact Person	Aaron Compton
Contact Person Address	541 Lakewood Dr., Fairview TX 75069
Contact Person Phone No.	214-533-1416
Contact Person email	acompton@vescodevices.com
Date Prepared	June 9th , 2023
Name of Medical Device	
Trade or proprietary name	DJF Intravascular Administration Set
Common or usual name	Intravascular Administration Set
Classification name	Set, Administration, Intravascular
Classification panel	General Hospital (80)
Regulation	21 CFR 880.5440
Product Code(s)	FPA
Device Classification	II
Legally marketed device(s) to which equivalence is claimed	K121803 – Intravascular Administration Set (ACTA Medical LLC)

Reason for 510(k)	**New devices to offer an alternative infusion set for use with the Curlin (MOOG) infusion pump.**
Device Description	**DJF Administration Sets are sterile/non-pyrogenic, single use, non-DEHP PVC tubing with a Universal Spike, Slide Clamp, Luer Lock (male) with integral anti-free flow valve (AFF) {optional, separately provided}, 0.2 micron or 1.2 micron filters, Yellow Cassette and Blue key (locator pin) for use with the Curlin IV pump. Three (3) new sets are:** **1. DJFCUR001: Administration set compatible with Curlin Pump** **2. DJFCUR002: Administration set with 0.2 micron filter compatible with Curlin Pump** **3. DJFCUR003: Administration set with 1.2 micron filter compatible with Curlin Pump**
Technological Characteristics	**The subject devices have the same technological material, fit, form and functional characteristics with predicate devices.**
Indications for Use	**DJF Intravascular Administration Sets are intended for use with Curlin (Moog) Infusion Pump, for the delivery of fluids from a container or bag to patient's vascular system**

Substantial Equivalence Summary

Feature	**Proposed Device DJF IV Administration Sets, K230992**	**Predicate Device K121803**	**Discussion**
Indications for use	DJF Intravascular Administration Sets are intended for use with Curlin (Moog) Infusion Pump, for delivery of fluids from a container or bag to patient's vascular system	Intravascular Administration Sets intended for delivery of fluids from a container or bag to patient's vascular system	Indications for use are fundamentally substantially equivalent
ABS Container Spike	ABS Container Spike, Non Vented	ABS Container Spike, Universal	Substantially Equivalent
PVC Tubing, TOTM	PVC Tubing, TOTM	PVC Tubing, TOTM	Substantially Equivalent
PVC Tubing, TOTM, Pump Segment	PVC Tubing, TOTM, Pump Segment	NA	Different See comment #1
Blue, ABS. Locator Pin	Blue. ABS, Locator Pin	NA	Different See Comment #2
Yellow, Flow Stop, ABS Box with 316L Spring	Yellow, Flow Stop, ABS Box with 316L Spring	NA	Different See Comment #3
ABS Male Luer	ABS Male Luer	ABS Male Luer	Substantially Equivalent

Slide Clamp	Slide Clamp	Slide Clamp	Substantially Equivalent
Sterilization, SAL 10^{-6}	Gamma Radiation, VDmax25	Gamma Radiation, VDmax25	SAL Substantially Equivalent

Comment/ Justification.

1. **Comment #1 =** The PVC tubing, TOTM, PUMP segment is different dimensionally from the predicate. However, the pump segment was tested in the performance testing using ISO 8536-4. A reference device was used to support this test method. Compatibility with the Moog Curlin infusion pump was assessed by the functional tests listed below. A reference device, K981816, was used to support these test methods.
2. **Comment #2** Blue ABS Locator Pin is not present in the predicate device as it's specific to use with the Moog Curlin infusion pump. It's an externally communicating component required for inserting the infusion set into the pump. Compatibility with the Moog Curlin infusion pump was assessed by the functional tests listed below. A reference device, K981816, was used to support these test methods.
3. **Comment #3** Yellow Flow stop ABS Box with 316L spring is not present in the predicate device as it's specific to use with the Moog Curlin Infusion Pump. It's an externally communicating component required for inserting the infusion set into the pump. Compatibility with the Moog Curlin infusion pump was assessed by the functional tests listed below. A reference device, K981816, was used to support these test methods.

1. **Performance Testing**

The sterile, single use DJF Intravascular Administration Sets intended for use with Curlin (Moog) Infusion Pump, described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards.

- ISO 80369-7:2016, Small-bore connectors for liquids and gases in healthcare applications- Part 7: Connectors for intravascular or hypodermic application.
- ISO 8536- 4: 2019, Infusion equipment for medical use-Part 4: Infusion sets for single use, gravity feed.

ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems

ASTM F1886/F1886M: 2016
Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

Additional functional testing was conducted to evaluate the administration set performance with Curlin (Moog) pump. The following functional tests were conducted:
-Rate Accuracy Test
-Set Installation Test
-Upstream Occlusion Test
-Downstream Occlusion Test
-Testing data demonstrates that no additional safety and effectiveness issues were identified in the use of the DJF Administration Sets with Curlin (Moog) pump. DJF sets performed substantially equivalent to reference predicate, OEM Curlin pump sets/

2. Biocompatibility Testing

In accordance with ISO 10993-1, the DJF Intravascular Administration Sets for Curlin (Moog) Infusion Set is classified as: Externally Communicating Device, Blood Path Indirect, Prolonged Contact (>24hrs to 30days). The following biocompatibility tests were conducted on DJF Curlin Pump compatible devices with and without filter:

a. Cytotoxicity
b. Hemolysis
c. Irritation
d. Acute Systemic Toxicity
e. Sensitization
f. Pyrogenicity
g. Sub-Acute/Sub-Chronic Systemic Toxicity
h. Endotoxin
i. Particulate Testing

3. Sterility, Shipping, Shelf Life

DJF Curlin Pump compatible devices have been validated for sterilization by Gamma Radiation, VDmax25 methodology in compliance with ISO 11137-3: 2017, Sterilization of Healthcare Products Shelf Life of 3 years has been assigned by testing product stored at normal storage environments. Shipping integrity has been tested with ASTM D4169-16 and shows no product damage.

Conclusion

The differences between the DJF Intravascular Administration Set and the predicate device do not raise any new or different questions of safety or effectiveness. The subject device is substantially equivalent with respect to the indications for use and technological characteristics.