January 21, 2021

Quest Medical, Inc.
Tosan Eweka
Regulatory Affairs Supervisor
One Allentown Parkway
Allen, Texas 75002

Re: K202672
Trade/Device Name: Precision Delivery Infusion Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: December 17, 2020
Received: December 18, 2020

Dear Tosan Eweka:

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,

CAPT Alan M. Stevens
Director (acting)
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)*
K202672

Device Name
Precision Delivery Infusion Sets

Indications for Use *(Describe)*
The Precision Delivery Infusion Sets are intended to be used to administer or aspirate fluids. These devices may be used with any patient population with consideration given to the procedure being performed and fluids being infused.

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) Notification K 202672

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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Contact Person:

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Date Prepared: September 17, 2020

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

Precision Delivery Infusion Sets

Generic/Common Name:

Intravascular Administration Set

Classification:

Class II per 21CFR§880.5440

Product Code:

FPA

PREDICATE DEVICE(S) [807.92(a)(3)]

Extension Sets with BD Q-Syte Luer Access Split Septum (K142527)

DEVICE DESCRIPTION [807.92(a)(4)]

Quest Medical's Precision Delivery Infusion Sets are single use, disposable, extension sets used to deliver fluids to a patient. The Precision Delivery Sets consist of various configurations, which includes tubing, filter, clamp, needleless connector and luers.

INDICATIONS FOR USE [807.92(a)(5)]

The Precision Delivery Infusion Sets are intended to be used to administer or aspirate fluids. These devices may be used with any patient population with consideration given to the procedure being performed and fluids being infused.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE [807.92(a)(6)]

The Precision Delivery Infusion Set has the same intended use, indications for use, and principles of operation and similar design features and technological characteristics as the predicate device. The differences in the technological characteristics between the Precision Delivery Infusion Set and the predicate device do not raise different questions of safety or effectiveness. Thus, the Precision Delivery Infusion Set is substantially equivalent to the predicate device. An analysis of the differences in technological characteristics is provided in the table below.

Element of Comparison	Predicate Device – Extension Sets with BD Q-Syte Luer Access Split Septum (K142527)	Subject Device	Analysis of Differences
Indications for Use	Extension Sets with an attached BD Q-Syte Luer Access Split Septum are intended to be used with intravascular catheters to aspirate blood or administer fluids, including medications and blood or blood products. These devices may be used with any patient population with consideration given to the procedure being performed and fluids being infused.	The Precision Delivery Infusion Sets are intended to be used to administer or aspirate fluids. These devices may be used with any patient population with consideration given to the procedure being performed and fluids being infused.	The main difference is the indications for use of the predicate is broader than the indications for use of the subject device. The predicate is indicated for aspiration and administration of blood, blood products and fluids while the subject device is indicated for administration or aspiration of fluids. The indications for the subject device falls within the indications for the predicate device. The difference in the

Element of Comparison	Predicate Device – Extension Sets with BD Q-Syte Luer Access Split Septum (K142527)	Subject Device	Analysis of Differences
			indications for use therefore does not alter the intended use of the predicate device and the subject device, which is to provide a conduit for the administration of fluids.
Design Features/Components	Tubing with Slide clamp, Needleless connector, Luers and Caps. Extension Sets are provided in single tubing, bifurcated tubing or trifurcated tubing configurations with lengths ranging from 5”-21”.	Tubing with Slide clamp, Needleless connector, Luers, Caps and Filter. Extension Sets are provided in single tubing and trifurcated tubing configurations with lengths ranging from 7”-62”.	The predicate device and subject device are both offered in single and trifurcated tubing configurations. The predicate device additionally has a bifurcated tubing configuration. The subject device is not offered in bifurcated models. The predicate device and subject device are comprised of the same component types with the exception of a filter component included in the subject device. The fluid filter in the subject device is intended to filter particulates. Fluid filter efficiency test was conducted on the subject device and all acceptance criteria was met. The minimum/maximum length configuration of the subject device is shorter/longer than the predicate device. The results from performance testing conducted on the subject device demonstrates that the

Element of Comparison	Predicate Device – Extension Sets with BD Q-Syte Luer Access Split Septum (K142527)	Subject Device	Analysis of Differences
			difference in design features and components between the subject device and predicate device do not raise different questions of safety and effectiveness. The subject device met all performance specifications necessary to fulfil its intended use.
Mode of Fluid Delivery	Gravity	Same	No difference
Device Materials	Tubing • Non-DEHP PVC Slide clamp • Unknown Luer Cap • Unknown Needleless Connector • Unknown Luers • Unknown	Tubing • Non-DEHP PVC Slide clamp • HDPE Luer Cap • HDPE Filter • Acrylic/PTFE/PES Needleless Connector • Polycarbonate/Silicone Luers • ABS/Co-Polyester	The subject device tubing and predicate device tubing are made from Non-DEHP PVC. The materials used on other components of the predicate device is unknown. Results from biocompatibility testing conducted on the subject device demonstrate that differences (if any) in the materials used in the subject device and predicate device do not raise different questions of safety and effectiveness.
Patient Contact Category/Duration	Externally Communicating, Blood Path Indirect, Prolonged contact	Same	No difference
Sterilization	SAL 10^{-6}	Same	No difference

PERFORMANCE DATA [807.92(b)]

All necessary testing was conducted on the Precision Delivery Infusion Sets to support a determination of substantial equivalence to the predicate device.

Nonclinical Testing Summary [807.92(b)(1)]

The bench and nonclinical tests conducted on the Precision Delivery Infusion Sets in this submission included:

- Priming Volume
- Backpressure Leak
- Flow Rate
- Simulated Maximum Use
- Tubing Bond Strength
- Multiple Clamping
- Prolonged Clamping
- Tubing Kink Resistance
- Aspiration Test
- ISO 8536-4 Chemical and Particulate Tests
- ISO 8536-4 Filter Efficiency Test
- ISO 80369-7:2016 Luer compliance
- USP <788> Particulate Test
- Biocompatibility Tests (Cytotoxicity, Sensitization, Irritation, Pyrogenicity, Hemocompatibility, Acute Systemic Toxicity, Sub-Chronic Toxicity)
- Sterilization validation per ISO 11135:2014
- Bacterial Endotoxin Tests

Microbial ingress data for the needleless connector component was referenced to the previously cleared K002689.

Clinical Testing Summary [807.92(b)(2)]

Not applicable. Clinical testing was not performed to support this 510(k) submission.

CONCLUSIONS [807.92(b)(3)]

The collective results of the performance testing demonstrate that the Precision Delivery Infusion Sets meets the established specifications necessary for consistent performance during its intended use. In addition, the collective performance testing demonstrate that the Precision Delivery Infusion Sets does not raise different questions of safety or effectiveness when compared to the predicate device. The results from the performance testing support the conclusion that the Precision Delivery Infusion Sets is substantially equivalent to the predicate device.

SUMMARY

The Precision Delivery Infusion Sets is substantially equivalent to the predicate device.