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

Re: K213846
Trade/Device Name: Q2 Blood Administration Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: May 5, 2022
Received: May 6, 2022

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,

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)*
K213846

Device Name
Q2 Blood Administration Sets

Indications for Use *(Describe)*
The Blood Administration Sets are used to deliver blood, blood components, and IV fluids from a container to a patient's vascular system. These devices may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and the duration of therapy.

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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K213846-510K Summary

GENERAL INFORMATION

Date Prepared: June 6, 2022

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DEVICE INFORMATION

Trade Name: Q2 Blood Administration Set

Generic/Common Name: Intravascular Administration Set

Classification:	**Class II**
Regulation Number:	21CFR§880.5440
Product Code:	**FPA**

PREDICATE DEVICE(S)

K143082, B. Braun Medical IV Administration Sets with 200µm Blood Filter.

DEVICE DESCRIPTION

Quest Medical's Q2 Blood Administration Sets are single use, disposable intravenous administration sets used to deliver blood, blood components and IV fluids from a container to a patient's vascular system through the use of a hand pump or through gravity flow. The sets include tubing, bag spike, 200 micron blood filter drip chamber, luer connectors, clamps, hand pump, stopcock and needleless connector.

INDICATIONS FOR USE

Characteristics	**Predicate Device** IV Administration Sets with 200um Blood Filter K143082	**Subject Device** Q2 Blood Administration Sets K213846
Indication for Use	The IV Administration Sets with 200µm Blood Filter are used to deliver blood, blood components, and IV fluids from a container to a patient's vascular system. When the hand pump component is activated, the device is intended to deliver blood, blood products and crystalloid and colloid resuscitative fluids. These devices may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and the duration of therapy.	The Blood Administration Sets are used to deliver, blood components, and IV fluids from container to a patient's vascular system. The devices may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and the duration of therapy.
Prescription Only or over the Counter	Prescription Only	Prescription Only

Discussions of differences in Indications for Use statement

The subject device indications does not include the sentence "When the hand pump component is activated, the device is intended to deliver blood, blood products and crystalloid and colloid resuscitative fluids" which is included in the indications for the predicate device. The sentence describes the fluids delivered when using the hand pump component. It specifies crystalloid and colloid resuscitative fluids. Quest does not intend to make any compatibility claims on these fluids, hence it has been deleted from the indications statement of the subject device. Deleting this sentence does not change the overall intended use of both devices, which is administration of blood, blood components, and IV fluids to a patient. The difference in indications statements does not create a new intended use.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Q2 Blood Administration Sets has the same intended use, indications for use, and principles of operation as the predicate device, and has similar design features and technological characteristics as the predicate device. The table below outlines the similarities and differences between the subject device and the predicate device.

Element of Comparison	Predicate Device IV Administration Sets with 200um Blood Filter K143082	Subject Device Q2 Blood administration Set K213846	Analysis of Differences
Product Code	FPA	Same	Same
Regulation Number	21 CFR 880.5440	Same	Same
Regulation Name	Intravascular Administration Set	Same	Same
Class	II	Same	Same
Mode of Fluid Delivery	Gravity or Hand Pump Activation	Same	Same
Hand Pump Design	Cylindrical shape with ball check valves	Same	Same
Components	Tubing, drip chamber with 200 micron filter, bag spike, luer connector, roller clamp, slide clamp, hand pump, stopcocks, manifolds and/or luer access devices.	Tubing, drip chamber with 200 micron filter, bag spike, luer connector, roller clamp, slide clamp, pinch clamp, hand pump, stopcocks and luer access device	Different See Comment #1

Element of Comparison	Predicate Device – IV Administration Sets with 200um Blood Filter(K143082)	Subject Device	Analysis of Differences
Device Materials	Unknown	Vented Spike - LDPE Riblene FH20, Polyethylene and ABS Roller Clamp - ABS Tubing – Alpha Gary 2235L-78 not made with DEHP PVC 200 Micron Blood Filter Drip Chamber – DEHP Free PVC, Purell HP Polypropylene and PA Hand Pump - not made with DEHP PVC and Polypropylene Slide Clamp - Purell HP Polypropylene Pinch Clamp – Polypropylene, Flint Hills P5M6K-080 Spin Lock Male Luer - Terlux 2802 HD ABS Stopcock - HDPE, RX1805451118 Polycarbonate, LR 3003/40 Wacker Silicone, Blue Colorant K-75238 Female Luer - PVC AM22W17 Female Luer Cap - HDPE Chevron HD 9012 Y-Site with needleless connector- Polycarbonate and Silicone Solvent Code L – Dichloromethane and Cyclohexanone Solvent Code R – Methyl-Ethyl Ketone and Cyclohexanone	Different See Comment #2
Patient Contact Category/Duration	Externally Communicating, Blood Path Indirect, Prolonged contact	Same	Same
Sterilization	Ethylene Oxide	Same	Same
Tubing Length	Unknown	114” – 129”	See comment# 3
Priming Volume	Unknown	74mL – 76mL	See comment# 3
Needleless Connector Residual Volume	Unknown	0.09mL	See comment# 3

Discussions of differences in Technological Characteristics

Comment # 1: Components

The predicate device and subject device are comprised of the same components with the exception of a manifold in some configurations of the predicate device, which is not included in the subject device and use of pinch clamp in the subject device. Configurations of the predicate device without the manifold are therefore equivalent to the subject device. The additional pinch clamp used in the subject device performs the same functions as the slide clamp. The results from performance testing conducted on the subject device demonstrates that the difference in 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.

Comment # 2: Materials

The materials used on the predicate device is unknown. Materials used in the subject device are broadly used in medical devices and have been used on IV Admin and Extension Sets currently marketed by Quest Medical. 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.

Comment # 2: Tubing Length, Priming Volume and Residual Volume

The tubing length, priming volume and residual volume of the predicate device is unknown. Results from performance qualification testing conducted on the subject device demonstrate that these differences (if any) between the predicate device and the subject device do not raise different questions of safety and effectiveness as all acceptance criteria were met.

PERFORMANCE DATA

All necessary bench and nonclinical testing was conducted on the Q2 Blood Administration Sets to support a determination of substantial equivalence to the predicate device.

Nonclinical Testing Summary

A. Performance Test- Bench

The bench and nonclinical tests conducted on the Q2 Blood Administration Sets in this submission are summarized below. The subject device met the applicable test specifications/acceptance criteria as described in the submission.

- ISO 1135-4:2015 Transfusion equipment for medical use-Part 4: Transfusion sets for single use, gravity feed
- ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications-Part 7: Connectors for Intravascular or hypodermic applications
- Particulate matter testing was conducted in accordance with USP <788>Particulate Matter in Injections and met the USP acceptance criteria.
- Mechanical Hemolysis Test

B. Biocompatibility

In accordance with ISO 10993-1, the Q2 Blood Administration Set, the proposed device were classified as: Externally Communicating Device with Direct Blood contact for Prolonged Contact Duration (>24hrs -30days.). The following Testing was conducted:

- Cytotoxicity
- Sensitization
- Irritation
- Hemocompatibility
- Acute Systemic Toxicity
- Sub-Chronic Toxicity
- Genotoxicity

C. Sterility, Shipping, and Shelf-Life

The subject device is intended to be sterilized with Ethylene Oxide procedures validated per ISO 11135:2014. The subject device met applicable acceptance criteria for EO residuals per ISO 10993-7:2008 and pyrogenicity (LAL method) per USP <161>. The following additional tests were conducted:

- Sterile Barrier Packaging Testing (ASTM F1140 Burst Test, Peel Test and ASTM F1929 Dye Penetration Test).
- 3 year shelf-life test per ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
- Simulated Shipping per ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and System.

Microbial ingress data for the needleless connector component used on the Q2 Blood Administration Sets was referenced to the previously cleared K002689.

Clinical Testing Summary

Not applicable. Clinical testing was not performed to support these 510(k) submissions.

CONCLUSIONS

The collective results of the performance testing demonstrate that the Q2 Blood Administration Sets meets the established specifications necessary for consistent performance during its intended use. In addition, the collective performance testing demonstrate that the Q2 Blood Administration Sets do 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 Q2 Blood Administration Sets is substantially equivalent to the predicate device.