June 2, 2022

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

Re: K213588
Trade/Device Name: Q2 IV Administration Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPA
Dated: May 2, 2022
Received: May 3, 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)*
K213588

Device Name
Q2 IV Administration Sets

Indications for Use *(Describe)*
IV Administration Sets are intended for delivery of fluids from a container into 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 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.

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510(k) Notification K213588

GENERAL INFORMATION [807.92(a)(1)]

Applicant:
Quest Medical, Inc.
One Allentown Parkway
Allen, TX 75002-4211
USA
Phone: 972-332-6338
Fax: 972-390-2881

Contact Person:
Tosan Eweka
Regulatory Affairs Manager
Quest Medical, Inc.
One Allentown Parkway
Allen, TX 75002-4211
USA
Phone: 972-332-6338
Fax: 972-390-2881
Email: teweka@questmedical.com

Date Prepared: November 9, 2021

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

Q2 IV Administration Sets

Generic/Common Name:

Intravascular Administration Set

Classification:

Class II per 21CFR§880.5440

Product Code:

FPA

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

B.Braun Medical IV Administration Sets (K170595)

DEVICE DESCRIPTION [807.92(a)(4)]

Quest Medical's Q2 IV Administration Sets are single use, disposable intravenous administration sets used to deliver fluids from a container into a patient's vascular system. These sets may be comprised of various components including insertion spike, drip chamber, clamp, check valve, stopcock, tubing, luer connections and needleless connector.

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

The IV Administration Sets are intended for delivery of fluids from a container into 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 duration of therapy.

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

The Q2 IV 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 – Extension Sets with B.Braun Medical IV Administration Sets(K170595)	Subject Device	Analysis of Differences
Product Code	FPA	FPA	Same
Regulation Number	21 CFR 880.5440	21 CFR 880.5440	Same
Regulation Name	Intravascular Administration Set	Intravascular Administration Set	Same
Class	II	II	Same
Indications for Use	The IV Administration Sets are intravenous administration sets intended for delivery of fluids from a container into 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 duration of therapy.	The IV Administration Sets are intended for delivery of fluids from a container into 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 duration of therapy.	Removed "intravenous administration sets" from the subject device indications to avoid repetition. There is no difference in the actual indications for use. The indications for use for the subject device and predicate device are therefore substantially equivalent.
Components	Insertion spike drip chamber tubing luer connections manifold needleless connector stopcocks clamps check valve	Insertion spike drip chamber tubing luer connections needleless connector stopcocks clamps check valve	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. Configurations of the predicate device without the manifold are therefore substantially equivalent to the subject device. 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.
Mode of Fluid Delivery	Gravity	Gravity	Same
Control Mechanism	Clamps and Stopcock	Clamps and Stopcock	Same
Compatibility with Blood and Blood Products	Not intended for use with blood or blood products per IFU	The subject device is not intended to be used with blood or blood products	Same
Sterilization	Ethylene Oxide, SAL 10^{-6}	Ethylene Oxide, SAL 10^{-6}	Same

Element of Comparison	Predicate Device – Extension Sets with B.Braun Medical IV Administration Sets(K170595)	Subject Device	Analysis of Differences
Device Materials	Unknown	Tubing - Alpha Gary 2235L-78 PVC not made with DEHP Vented drip chamber • Alpha Gary 2235L-78 PVC not made withDEHP • ABS • HDPE • LDPE • Lexan polycarbonate and 304 stainless steel. Check valve – Plexiglas DR100, DR6602, Silicone Needless Connector y-site-Makrolon RX 1805-451118 Polycarbonate, LR3003/40 Silicone Pinch clamp – Polypropylene Roller clamp – ABS Male luer - Eastman Tritan MX-731 Copolyester Female luer - Eastman DN003 Copolyester Male Luer - ABS Terlux PP Purell HP317P Stopcock - Makrolon RX 1805- 451118 Polycarbonate, LR3003/40 Silicone, HDPE Solvent 20/80 Code R - Cyclohexanone, Methyl Ethyl Ketone	The materials used on components of the predicate device is unknown. Materials used in the subject device are identical to those used in currently marketed Quest IV Administration Sets. 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	Externally Communicating, Blood Path Indirect, Prolonged contact	Same
Shelf-Life	Unknown	1 year	The shelf life of the predicate device is unknown. The subject device was qualified with 1 year shelf life and all acceptance criteria were met. Results from shelf life testing conducted on the subject device demonstrate that differences (if any) between the shelf life of the predicate device and the subject device shelf life do not raise different questions of safety and effectiveness.
Tubing length	Unknown	102”- 118”	The tubing length of the predicate device is unknown. Results from product performance qualification testing conducted on the subject device demonstrate that differences (if any) between the tubing length of the predicate device and the subject device do not raise different questions of safety and effectiveness.

Discussions of differences in Components

The component used in the various configurations of the predicate device and subject device are similar. The main difference between the components used on the predicate device and those used on the subject device is the inclusion of manifold in some configurations of the predicate device, which is not included in the subject device. Configurations of the predicate device without the manifold are therefore substantially equivalent to the subject device. The results from performance qualification 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.

Discussions of differences in Materials

The materials used on the predicate device is unknown. Materials used in the subject device are identical to those used in currently marketed Quest IV Administration Sets. Additionally, results from biocompatibility testing conducted on the subject device demonstrate that differences (if any) between the materials used in the subject device and those used in the predicate device do not raise different questions of safety and effectiveness.

Discussions of differences in Shelf Life

The shelf life of the predicate device is unknown. The subject device was qualified with 1 year shelf life and all acceptance criteria were met. Results from shelf life testing conducted on the subject device demonstrate that differences (if any) between the shelf life of the predicate device and the subject device shelf life do not raise different questions of safety and effectiveness.

Discussions of differences in Tubing Length

The tubing length of the predicate device is unknown. The tubing length of the subject device ranges from 102”- 118”. Results from performance qualification testing conducted on the subject device demonstrate that differences (if any) between the tubing length of the predicate device and the subject device do not raise different questions of safety and effectiveness as all acceptance criteria were met.

PERFORMANCE DATA [807.92(b)]

All necessary bench, nonclinical, and human factors testing was conducted on the Q2 IV Administration 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 Q2 IV Administration Sets in this submission included:

- Maximum Simulated Use Test

- Flow Rate Test
- High Pressure Leak Test
- Vacuum Pressure Leak Test
- Closure Piercing Device Test
- Air Inlet Device Test
- Drip Chamber Test
- Flow Regulator Test
- Tubing Bonding Strength Test
- Priming Volume Test
- Spike Cap Retention Test
- ISO 8536-4 Chemical Test
- USP <788> Particulate Test
- Biocompatibility Tests (Cytotoxicity, Sensitization, Irritation, Hemocompatibility, Acute Systemic Toxicity, Sub-Chronic Toxicity, Genotoxicity)
- EO Residual Test
- Bacterial Endotoxin Test
- ISO 80369-7:2016 Luer compliance

Microbial ingress data for the needleless connector component used on the Q2 IV Admin Sets 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 Q2 IV Administration Sets meets the established specifications necessary for consistent performance during its intended use. In addition, the collective performance testing demonstrate that the Q2 IV Administration 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 Q2 IV Administration Sets is substantially equivalent to the predicate device.

SUMMARY

The Q2 IV Administration Sets is substantially equivalent to the predicate device.