DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 8, 2017

Quest Medical, Inc.
Amy Clendening-Wheeler
Senior Regulatory Affairs Specialist
One Allentown Parkway
Allen, TX 75002

Re: K162804
Trade/Device Name: Q2® Low Pressure Power Injection Extension Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Sets
Regulatory Class: Class II
Product Code: FPA
Dated: February 3, 2017
Received: February 6, 2017

Dear Amy Clendening-Wheeler:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mary E. Brooks -A

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162804

Device Name
Q2 Low Pressure Power Injection Extension Set

Indications for Use *(Describe)*
Pressure Rated: The Q2 Low Pressure Power Injector Extension Set with needleless connector is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration. This set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10ml per second.
Non Pressure Rated: The Q2 Low Pressure Power Injector Extension Set with needleless connector is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration.

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 K162804

DATE PREPARED: March 8, 2017

SUBMITTER: Quest Medical, Inc.
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Contact: Amy Clendening-Wheeler
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DEVICE NAME: Q2® Low Pressure Power Injection Extension Set

COMMON NAME: IV Extension Sets

CLASSIFICATION NAME: Intravascular Administration Sets

PRODUCT CODE: FPA

REGULATION: 880.5440

CLASS: II

PREDICATE DEVICE: Carefusion MaxPlus® Pressure Rated Extension Set with removable clear needleless connector (K140831)

REFERENCE DEVICE: Quest Medical Inc. Q2® Multiport IV Administration Sets and Extension Sets and CheckMate® IV Administration Sets and Extension Sets (K162304)

DESCRIPTION: Sterile, single use non-pyrogenic intravenous administration extension set comprised of 7 inch tubing bonded to a male luer on one end and a female luer on the other end with a clamp in between. A swabable, needle-free port is connected to the female luer. This device is not made with the plasticizer Diethylhexylphthalate (DEHP).

INTENDED USE: For administration of intravenous fluids to a patient's vascular system utilizing needle-free components and provide short-term intravascular or subcutaneous access using a variety of infusates (i.e. anesthesia

drugs, chemotherapeutics, drugs, antibiotics, blood products, commonly used prep solutions). The device may also be used with low pressure power injectors rated for a maximum setting of 325 psi.

INDICATIONS FOR USE: Pressure Rated: The Q2 Low Pressure Power Injector Extension Set with needleless connector is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration. This set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10ml per second.

Non Pressure Rated: The Q2 Low Pressure Power Injector Extension Set with needleless connector is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration.

SUBSTANTIAL EQUIVALENCE

Bench Testing

Functional performance testing including particulate testing per ISO 8536-4:2010, simulated shipping, package burst, priming volume, backpressure leak and flow rate for both normal and low pressure power injection use, and simulated maximum use for both normal and low pressure power injection use was completed for the proposed Q2 Low Pressure Power Injector Extension Set to demonstrate the device performs as intended and to manufacturer specification. Results of testing successfully demonstrate that the Q2 Low Pressure Power Injector Extension Set performs similarly to the predicate device to meet the functional requirements for both non-pressure use and low pressure power injection.

Sterilization

There is no change to the sterilization process for the proposed new Q2 Low Pressure Power Injection Extension Set from the other Quest Medical, Inc. IV Administration and Extension Set product family. The sterilization process is validated per ISO 11135 and Ethylene Oxide residuals testing was performed for the product line per ISO 10993-7:2008 “Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals.” Although the method of sterilization is different from the predicate device, both devices are sterile, non-pyrogenic, single-use devices with a minimum 10^{-6} SAL.

Shelf Life

Shelf life for the Q2 Low Pressure Power Injection Extension Set is qualified to 1 year. The predicate device is qualified to 5 years shelf life. The difference in shelf life is not a significant

difference as this attribute has no impact to the function of the device. The shelf life of each device is validated to meet each manufacturer's specification.

Biocompatibility

The materials of construction for the Model 95714 are identical to that of the Quest Medical Inc. Reference Devices of K162304, where the fully assembled representative IV Administration Set was tested according to ISO 10993-1:2009. Hemocompatibility, Cytotoxicity, Sensitization, Irritation/Intracutaneous Reactivity, Systemic Toxicity, Subchronic Toxicity, and Material-mediated Pyrogenicity tests were performed. Test results successfully verified that the IV Administration Set and Extension Set materials of construction are biocompatible for their clinical application.

Pyrogen

Pyrogen testing for bacterial endotoxins was performed via the kinetic chromogenic LAL (*Limulous Amebocyte Lysate*) method. The results found that the proposed new materials do not introduce a level of endotoxin that exceed established guidelines.

Comparison to Predicate:

The following table shows a comparison between the Q2® Low Pressure Power Injection Extension Set subject device to the Carefusion MaxPlus Pressure Rated Extension Set with removable clear needleless connector predicate device. The subject and predicate devices are similar in physical properties, materials, and configuration.

	Predicate Device	**Subject Device**
510(k)	K140831	K162804
Model #	MP5303-C	95714
Brand Name	MaxPlus Pressure Rated Extension Set with removable clear needleless connector	Q2 Low Pressure Power Injector Extension Set
Manufacturer	CareFusion	Quest Medical, Inc.
FDA Regulation Number	21CFR 880.5440 Intravascular Administration Set	SAME
FDA Class	II	SAME
FDA Product Code	FPA	SAME
Device Description	Intravascular extension sets intended for single patient use, including pediatrics and immunocompromised patients, for direct injection, intermittent infusion, continuous infusion or aspiration of drugs, blood, and fluids. The extension sets include a needleless connector to allow thorough and	The device is an intravascular extension set available in one configuration that includes a needleless connector. The device is not made with the plasticizer Diethylhexylphthalate (DEHP).

	Predicate Device	Subject Device
	easy disinfection due to a solid, flat, smooth surface and eliminates the risk of needlestick injuries. The extension sets are not made from natural rubber latex or DEHP. Configurations are available with needleless connectors, split septum ports, filters, stopcocks, manifolds, and/or T-connectors.	
Intended Use	For direct injection, intermittent infusion, continuous infusion or aspiration.	For administration of intravenous fluids to a patient's vascular system utilizing needle-free components and provide short-term intravascular or subcutaneous access using a variety of infusates (i.e. anesthesia drugs, chemotherapeutics, drugs, antibiotics, blood products, commonly used prep solutions). The device may also be used with low pressure power injectors rated for a maximum setting of 325 psi.
Indications for Use	Pressure Rated: The MaxZero multi fuse extension set with needleless connector(s) is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration. This set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10ml per second. Non Pressure Rated: The MaxZero multi fuse extension set with needleless connector(s) is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration.	Pressure Rated: The Q2 Low Pressure Power Injector Extension Set with needleless connector is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration. This set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10ml per second. Non Pressure Rated: The Q2 Low Pressure Power Injector Extension Set with needleless connector is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration. (SAME)
Device Design		
Components	Tubing, Luer, Check valve, Needleless Connector, Male spin lock connector Non-fluid contacting: Pinch clamp, vented female luer lock cap	SAME
Dimensions	Length: 7 inch (18cm)	SAME
Device Materials		
Tubing	PVC- Purple striped, non-DEHP, standard bore	Identical to Quest Medical, Inc. Reference Device K162304: PVC - clear, non-DEHP Alpha Gary 2235L-80, standard bore
Luer	Co-Polyester	Identical to Quest Medical, Inc. Reference

	Predicate Device	Subject Device
		Device K162304: Co-polyester
Needleless Connector	MaxZero Clear- Polycarbonate/silicone	Identical to Quest Medical, Inc. Reference Device K162304: SwabSite Valve – Polycarbonate/silicone
Male spin luer lock/hub	ABS thermoplastic	Identical to Quest Medical, Inc. Reference Device K162304: CYRO XT 250-301
Technology		
Use	Use with low pressure power injectors up to 325 psi and maximum flow rate of 10 mL/second	SAME
Priming volume	< 1 mL	1.0 mL
Energy Source	User Operated	SAME
Principle of Operation	Luer activation; direct injection, intermittent infusion, continuous infusion, aspiration	SAME
Sterilization and Package		
Method	Irradiation; E-Beam	100% EtO
Minimum SAL	1×10^{-6}	SAME
Packaging	Tyvek pouch	SAME
Shelf Life	5 year	1 year
Disposable or Reusable	Disposable	SAME

CONCLUSION:

Results of all functional performance testing conducted successfully demonstrate that the proposed new Q2 Low Pressure Power Injection Extension Set is substantially equivalent to the legally marketed predicate device.