



Food and Drug Administration
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September 30, 2015

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

Re: K151079
Trade/Device Name: Q2[®] Multiport IV Administration Sets and Extension Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA, FPK
Dated: April 20, 2015
Received: April 22, 2015

Dear Ms. 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 yours,

 Tina Kiang
-S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151079

Device Name

Q2 Multiport IV Administration Sets and Extension Sets

Indications for Use (Describe)

For administration of intravenous fluids to a patient's vascular system utilizing needleless components and an I.V. manifold for multiple simultaneous intravenous therapy via gravity, syringe, or infusion pump.

Use of a needle-free system may aid in the prevention of needle-stick injuries.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

DATE PREPARED September 29, 2015

SUBMITTER: Quest Medical, Inc.
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972-390-9800/800-627-0226

Contact: Amy Clendening-Wheeler, Sr. Regulatory Affairs Specialist
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DEVICE NAME: Q2® Multiport IV Administration Sets and Extension Sets

COMMON NAME: IV Administration Set

CLASSIFICATION NAME Intravascular Administration Set

Product Code: FPA, FPK

Regulation Number: 880.5440

Class: II

PREDICATE DEVICES: Quest Medical, Inc. Extension Sets (K800825)
Quest Medical, Inc. IV Administration Sets (K040385)

DESCRIPTION: Sterile, single use non-pyrogenic intravenous fluid administration sets with a multiport IV manifold and integrated back-check valves, pre-attached needleless injection sites, drip chamber and roller clamps. The reason for the submission was a material change to the male luer component.

INTENDED USE: For administration of intravenous fluids to a patient's vascular system utilizing needleless components and an I.V. manifold for multiple simultaneous intravenous therapy via gravity, syringe, or infusion pump.

Use of a needle-free system may aid in the prevention of needle-stick injuries.

SUBSTANTIAL EQUIVALENCE

Performance Testing

Sterilization

There is no change to the sterilization process for the proposed Q2® Multiport IV Administration Sets and Extension Sets. Ethylene Oxide residuals testing performed for the modified Male Luer made from Tritan MX711 complies with ISO 10993-7:2008 “Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals.”

Shelf Life

Shelf life for the proposed Q2® Multiport IV Administration Sets and Extension Sets was verified to remain the same as for the current Q2® Multiport IV Administration Sets and Extension Sets at 3 years.

Bench Testing

Functional performance testing including high pressure testing, bond strength testing, and solvent-exposure testing was completed with the proposed IV Administration Sets to demonstrate that the sets perform as intended. Results of testing successfully demonstrated that the proposed devices perform similarly to the predicate device.

Biocompatibility

The materials of construction of a fully assembled IV Administration Set were tested according to ISO 10993-1:2009. Test results successfully verified that the IV Administration Set materials of construction, including the male luer comprised of the Tritan MX-711 material, are biocompatible for their clinical application.

Comparison to Predicate:

The following table shows a comparison between the device components of the currently marketed Q2® Multiport IV Administration Sets and Extension Sets with the current Male Luer connector to the proposed Q2® Multiport IV Administration Sets and Extension Sets with new material Male Luer.

	Predicate Devices		Modified Device
510(k)	K800825	K040385	Under Review
Brand Name	Q2 Extension Set	Q2 Multiport® Manifold IV Set with Swabable Valves	SAME
Model #	95902	9520, 9525A, 9526B, 9527B, 22-201-V	SAME
Manufacturer	Quest Medical, Inc.		SAME
Device Description	Q2 extension sets and iv administration sets are sterile, non-pyrogenic, single-use intravenous fluid delivery devices. Some models have a multiport IV manifold with backcheck valves, pre-attached needleless injections sites, drip chamber and roller clamps. They are non-invasive devices for short-term use. They deliver either a single infusate or multiple infusates		SAME

	Predicate Devices	Modified Device
	based on the clinical need of the customer.	
Clinical Use	The devices are used by clinicians in a variety of clinical settings such as operating rooms, chemotherapy regimens, ICUs, ext. The devices have direct patient contact due to the administration of fluids to the vascular system. A variety of infusates such as anesthesia drugs, chemotherapeutics, total parental nutrition (TPN) drugs, antibiotics, etc. The devices themselves do not have any intended therapeutic claim.	SAME
Intended Use/ Indications for Use	For administration of intravenous fluids to a patient's vascular system utilizing needleless components and an I.V. manifold for multiple simultaneous intravenous therapy via gravity, syringe, or infusion pump. Use of a needle-free system may aid in the prevention of needle-stick injuries.	SAME
Materials		
Male Luer	Acrylic Cyro MED-2 plastic	Eastman Tritan MX-711
Tubing	PVC	Identical
6 port Manifold	Polycarbonate housing, silicone stem, polyisoprene checkvalve	Identical
Filter	Copolyester housing, Durapel PVDF, Polyestersulfone	Identical
Swabable Y-site	Polycarbonate and silicone	Identical
Inline checkvalve	Plexi-Glas	Identical
Drip Chamber	PVC	Identical
Spike	PVC, ABS, PP, LDPE	Identical
Technology		
Energy Source	User Operated	Identical
Principle of Operation	Luer activation	Identical
Sterilization/Pkg		
Method	EtO, 100%	Identical
Minimum SAL	1×10^{-6}	Identical
Packaging	Tyvek polyethylene; heat-sealed	Identical
Shelf Life	Three (3) Years	Identical
Disposable or Reusable	Disposable	Identical

CONCLUSION:

Results of functional performance and biocompatibility testing conducted with the proposed and predicate devices demonstrate that the Q2® Multiport IV Administration Sets and Extension Sets are substantially equivalent to the legally marketed predicate device.