December 6, 2016

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

Re: K162304
Trade/Device Name: Q2® Multiport IV Administration Sets and Extension Sets
Checkmate® 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: November 9, 2016
Received: November 10, 2016

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,

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

510(k) Number (if known)  
K162304

Device Name  
Q2 Multiport IV Administration Sets and Extension Sets  
CheckMate IV Administration Sets and Extensions Sets

Indications for Use (Describe)  
The Q2 and CheckMate Multiport IV Administration Sets and Extension Sets are indicated for use for the following:  
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.”

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRASstuff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

FORM FDA 3881 (8/14)  
Page 1 of 1

[No PSC Publishing Services info available]
DATE PREPARED: December 5, 2016

SUBMITTER: Quest Medical, Inc.
One Allentown Parkway
Allen, TX 75002 USA
972-390-9800/800-627-0226

Contact: Amy Clendening-Wheeler
Phone:  (972) 332-6228
Fax:  (469) 795-2338
Email: awheeler@questmedical.com

DEVICE NAME: Q2® Multiport IV Administration Sets and Extension Sets
CheckMate® IV Administration Sets and Extension Sets

COMMON NAME: IV Administration Sets

CLASSIFICATION NAME: Intravascular Administration Sets

PRODUCT CODE: FPA, FPK

REGULATION: 880.5440

CLASS: II

PREDICATE DEVICES: Quest Medical, Inc. Q2 Multiport IV Administration Sets and Extension Sets (K151079, K800825) and CheckMate IV Administration Sets and Extension Sets (K040385)

DESCRIPTION: Sterile, single use non-pyrogenic intravenous fluid administration sets which may include a multiport IV manifold, integrated back-check valves, pre-attached needleless injection sites, drip chamber and roller clamps. The subject devices for this Premarket Notification are manufactured with tubing and drip chamber materials not made with the plasticizer Diethylhexylphthalate (DEHP).

INDICATIONS FOR USE: The Q2 and CheckMate Multiport IV Administration Sets and Extension Sets are indicated for use for the following:
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**

*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 devices.

*Sterilization*

There is no change to the sterilization process for the proposed Q2 and CheckMate Multiport IV Administration Sets and Extension Sets. Ethylene Oxide residuals testing performed for the devices manufactured with the proposed non-DEHP polyvinyl chloride tubing formulations and non-DEHP Drip Chamber complies with ISO 10993-7:2008 “Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals.”

*Shelf Life*

Shelf life for the Q2 and CheckMate Multiport IV Administration Sets and Extension Sets manufactured with the proposed non-DEHP polyvinyl chloride tubing formulations and non-DEHP Drip Chamber was verified to remain the same as for the current Q2 and CheckMate Multiport IV sets and Extension Sets at 3 years.

*Biocompatibility*

The materials of construction of a fully assembled representative IV Administration Set were 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 materials of construction, including the proposed new non-DEHP polyvinyl chloride tubing formulations and non-DEHP Drip Chamber, are biocompatible for their clinical application.
**Pyrogen**

Pyrogen testing for bacterial endotoxins was performed via the kinetic chromogenic LAL (*Limulus 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 device components of the currently marketed Q2 and CheckMate Multiport IV Administration Sets and Extension Sets with the current PVC tubing and PVC Drip Chamber to the Q2 and CheckMate Multiport IV Administration sets and Extension Sets manufactured with the proposed non-DEHP polyvinyl chloride tubing formulations and non-DEHP Drip Chamber.

<table>
<thead>
<tr>
<th>Predicate Device</th>
<th>Modified Device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>510(k)</strong></td>
<td>K151079</td>
</tr>
<tr>
<td><strong>Model #</strong></td>
<td>9520, 9525A, 9525B, 9527B, 95902, 22-201V</td>
</tr>
<tr>
<td><strong>Brand Name</strong></td>
<td>Q2 Multiport IV Administration Sets and Extension Sets</td>
</tr>
<tr>
<td><strong>Manufacturer</strong></td>
<td>Quest Medical, Inc.</td>
</tr>
<tr>
<td><strong>Device Description</strong></td>
<td>Q2 and Checkmate Multiport IV Administration Sets and Extension 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 based on the clinical need of the customer.</td>
</tr>
<tr>
<td><strong>Clinical Use</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Intended Use/Indications for Use</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>

SAME
<table>
<thead>
<tr>
<th><strong>Predicate Device</strong></th>
<th><strong>Modified Device</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of a needle-free system may aid in the prevention of needlestick injuries.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Materials</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Male Luer</strong></td>
<td>Eastman Tritan MX-711</td>
</tr>
<tr>
<td><strong>Tubing</strong></td>
<td>PVC, Colorite 5004A, clear</td>
</tr>
<tr>
<td><strong>Swabable Y-site</strong></td>
<td>Polycarbonate and silicone</td>
</tr>
<tr>
<td><strong>Inline checkvalve</strong></td>
<td>Plexi-Glas</td>
</tr>
<tr>
<td><strong>Filter</strong></td>
<td>Copolyester housing, Durapel PVDF, Polyesstersulfone</td>
</tr>
<tr>
<td><strong>Drip Chamber Barrel</strong></td>
<td>PVC: PTV-402-BT 1 clear</td>
</tr>
<tr>
<td><strong>Spike</strong></td>
<td>PVC, ABS, PP, LDPE</td>
</tr>
<tr>
<td><strong>6 port Manifold</strong></td>
<td>Polycarbonate housing, silicone stem, polyisoprene checkvalve</td>
</tr>
<tr>
<td><strong>Technology</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Energy Source</strong></td>
<td>User Operated</td>
</tr>
<tr>
<td><strong>Principle of Operation</strong></td>
<td>Luer activation</td>
</tr>
<tr>
<td><strong>Sterilization/Pkg</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Method</strong></td>
<td>EtO, 100%</td>
</tr>
<tr>
<td><strong>Minimum SAL</strong></td>
<td>$1 \times 10^{-6}$</td>
</tr>
<tr>
<td><strong>Packaging</strong></td>
<td>Tyvek polyethylene/Mylar pouch; heat-sealed</td>
</tr>
<tr>
<td><strong>Shelf Life</strong></td>
<td>Three (3) Years</td>
</tr>
<tr>
<td><strong>Disposable or Reusable</strong></td>
<td>Disposable</td>
</tr>
</tbody>
</table>

**CONCLUSION:**

Results of all functional performance and biocompatibility testing conducted successfully demonstrate that the Q2 and CheckMate Multiport IV Administration Sets and Extension Sets manufactured with the proposed non-DEHP patient-contacting tubing formulations and non-DEHP Drip Chamber are substantially equivalent to the legally marketed predicate devices.