K040385

APR - 7 2004

Section 11

510(k) Summary of Safety and Effectiveness

1. **SUBMITTER INFORMATION:**

Submitter's Name:	Quest Medical, Inc.
Address:	One Allentown Parkway Allen, Texas 75002
Telephone:	972-390-9800
Fax Number:	972-390-2881
Contact Person:	Kathryn J. Thompson
Date Prepared:	1 April 2004

2. **DEVICE INFORMATION:**

Proprietary Name:	Multiport® Manifold I.V. Set with Swabable Valves
Common/Usual Names:	Intravascular Administration Sets, I.V. Sets
Classification:	Class II, 21 CFR 880.5440

PREDICATE DEVICE: Baxter Continu-Flo Solution Set, 2C8930, K003225

3. **DEVICE DESCRIPTION:**

Sterile single use, non-pyrogenic intravenous fluid administration set: 85 in. (216 cm) long, multiport IV manifold with integrated back check valves, pre-attached needleless injection sites, drip chamber, roller clamps.

4. **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.

5. **SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF NEW DEVICE TO PREDICATE DEVICE:**

The technological characteristics of the Multiport IV Set do not differ significantly from the currently marketed Baxter Continu-Flo set. The devices use the same fundamental scientific technology and have the same intended use.

6. **NON-CLINICAL TEST CONCLUSIONS:**

The results of laboratory testing (design verification) using the FDA guidance for Intravascular Administration Sets demonstrate acceptable performance of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2004

Quest Medical, Incorporated
C/O Mr. Jeremi Peck
Responsible Third Party Official
Underwriters Laboratories Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

Re: K040385
Trade/Device Name: Multiport® Manifold I.V. Set 3 with Swabable Valves
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: March 16, 2004
Received: March 23, 2004

Dear Mr. Peck:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-5618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for, Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040385

SECTION 5
INDICATIONS FOR USE STATEMENT

510(k) Number:

Device Name: Multiport® Manifold I.V. Set with Swabable Valves

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.

I1 ⟶ The needleless safety feature may aid in the prevention of needlestick injury.

(Please do not write below this line—continue on another page if needed)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use ✓ **OR** Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040385