SEP - 2 2004

K041979

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. SUBMITTER INFORMATION:

Name:	Quest Medical, Inc
Address:	One Allentown Parkway
Telephone:	972-390-9800 x 320
Fax Number:	972-390-2881
Contact Person:	Jane Ann Martin, RA Mgr.
Date Prepared:	August 9, 2004

2. DEVICE INFORMATION:

Proprietary Name:	MPS® 2 Myocardial Protection System Console
Common/Usual Names:	Myocardial Perfusion System
Classification:	Class II, 21 CFR 870.4240

3. PREDICATE DEVICE: MPS Myocardial Protection System: K994274

4. DEVICE DESCRIPTION:

The MPS 2 console is a single device for myocardial perfusion that incorporates several different functions: heat exchanger, temperature control, pressure control, flow rate control, automatic priming and air detection / removal, and 3 flow modes – normal, cyclic, low volume.

5. INTENDED USE

The MPS System, MPS console and the MPS delivery set used together, is for use by perfusionists and physicians to deliver whole blood (from any arterial source and/or cardioplegia solutions to the heart during open heart surgery on either an arrested or beating heart for use up to six hours in duration.

6. TECHNOLOGICAL CHARACTERISTICS: From FDA memo #K86-3 flowchart:

1 – Does new device have the same indication statement? Yes. The MPS 2 has the same intended use as the predicate.

2 – Does the new device have the same technological characteristics? No. The modified device has additional user options.

3 – Could the new characteristics affect safety or effectiveness? Yes.

4 – Do the new characteristics raise new type of safety or effectiveness questions? No. The safety and effectiveness questions are the same as for the predicate

5 – Do accepted scientific methods exist for assessing effects of the new characteristics? Yes. The same in-house test methods were used as in the original 510(K) submission. UL Laboratories testing methods were used for the electrical / EMI evaluations.

6 – Is performance data available to assess effects of new characteristics? Yes. In-house performance testing data, including simulated use testing, and UL testing data for certification to UL/IEC 60601-1: 2003 and EN/IEC 60601-1-2:2001 are available.

7– Does performance data demonstrate equivalence? Yes. The MPS 2 console passed all in-house testing acceptance criteria. UL certified the MPS 2 console as conforming to IEC 60601-1-2:2002 and UL 60601-1:2003 standards.

7. CONCLUSION: The MPS 2 console is substantially equivalent to the MPS console.

® MPS is a registered trademark of Quest Medical, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2004

Quest Medical, Inc.
c/o Ms. Jane Ann Martin
Regulatory Affairs Manager
One Allentown Parkway
Allen, TX 75002

Re: K041979
MPS® 2 Myocardial Protection System
Regulation Number: 21 CFR 870.4240
Regulation Name: Cardiopulmonary Bypass Heat Exchanger
Regulatory Class: Class II (two)
Product Code: DTR
Dated: August 9, 2004
Received: August 10, 2004

Dear Ms. Martin:

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) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ___K041979_____

Device Name: _____MPS® 2 Myocardial Protection System_

Indications for Use:

The Quest Medical MPS® 2 Myocardial Protection System, consisting of the MPS 2 Console and the MPS Delivery Set together, is intended for use by perfusionists and physicians to deliver whole blood (from any arterial source) and / or cardioplegia solutions to the heart during open heart surgery on either an arrested or beating heart for use up to six hours in duration

Prescription Use _____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Vochniak

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041979