K994274

MAY 3 1 2000

SUMMARY OF SAFETY AND EFFECTIVENESS

QUEST MYOCARDIAL PROTECTION SYSTEM PERFUSION ASSISTED DIRECT CORONARY ARTERY BYPASS (PADCAB)

I. General Information

A. Generic Name:	Cardioplegia Delivery System
B. Trade Name of Device:	MPS® Perfusion Assisted Direct Coronary Artery Bypass (PADCAB)
C. Applicant's Name and Address:	Quest Medical, Inc. One Allentown Pkwy Allen, TX 75002
D. Premarket Notification Number:	Not assigned to date

II. Indication for Use

The Quest Myocardial Protection System, consisting of the MPS Console and the MPS Delivery Set used together, is intended for use by perfusionist 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

III. Device Description

The MPS is designed to deliver whole blood or cardioplegia solution. The MPS pumping subsystem coordinates the pumping and mixing of the blood and additives to deliver the desired composition of cardioplegia solution. The pumping subsystem consist of an electro-mechanical pumping device acting on a variety of disposable cassettes to deliver fluid. A set of four pump pistons, each driven by a stepper motor, displace the contents of the mechanically restrained fluid filled cassettes. Pressure sensors located on the end of each piston diagnose the adequacy of the pumping and filling process. The main blood pump consist of two motor driven pistons and a symmetrically designed pump cassette with two chambers. Each chamber is designed to alternately fill and pump blood. A set of valves operate on channels formed within the cassette to control the flow of fluids into and out of the chamber. As one chamber is filled, the other chamber is delivering solutions. This overlapping and alternating operation of the pumping system provides an essentially constant fluid output

IV. Device Classification: Class II

Quest Myocardial Protection System PADCAB is reviewed by the FDA Cardiovascular (CV) and (HO) General Hospital Classification Panels. The Product Classification Codes and Panel Codes for this device and predicate devices are:

80 DWK Pump, Infusion, Cardiovascular	21 CFR 880.5725
74 DTR Cardiovascular bypass, Heat exchanger	21 CFR 870.4240
74 DRS Transducer, Blood-Pressure, Extravascular	21 CFR 870.285
74 DXS Cardiopulmonary bypass coronary pressure gauge	21 CFR 870.4310
74 DWF Cardiopulmonary bypass vascular catheter, cannula, or tubing	21 CFR 870.4210
74 KRL Cardiopulmonary bypass bubble detector	21 CFR 870.4205

V. Safety and Effectiveness

Substantial Equivalence:
This device has been shown to be substantially equivalent to the Quest MPS Myocardial Protection System #k953838

VI. Other Safety and Effectiveness Data

Materials:	Fluid contact materials are comply with ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing" for short term devices.
Sterilization:	Validated Ethylene Oxide Sterilization per AMI / ISO 11135 – 1994 and EN 550 SAL of 10^{-6}
Pyrogenicity:	Non-Pyrogenic per USP Pyrogen Test (LAL)

Functional Test

The function test data to support the safety and efficacy of the device has not changed from the predicate device submission. Please refer to paragraph 3 of pages 15 – 16 of TAB 20 of Volume 4 of original submission (#k953838). A copy has been enclosed for your convenience.

SUMMARY OF SAFETY AND EFFECTIVENESS

V. Safety and Effectiveness

Substantial Equivalence:

The device has been shown to be substantially equivalent to the Sarns' Integrated Cardioplegia Delivery System (ICDS) #K810079, Sarns Conducer Heat Exchanger # K923311, Avecor Heat Exchanger # K904171, Stockert-Shiley Low Level Detector Bubble Monitor # K864619, Shiley Temperature Monitor # 802147and the Stockert-Shiley Dual Pressure Control Module # K862836.

VI. Other Safety and Effectiveness Data:

Materials:	Fluid contact materials of construction comply with ISO-10993 " Biological Evaluation of Medical Devices - Part 1 : Evaluation and Testing" for short term devices.
Sterilization:	Validated METHOD-1 Radiation Sterilization SAL 10^{-6}
Pyrogenicity:	Non-Pyrogenic per USP Pyrogen test (LAL)

Functional Testing

Leak Test Requirements	No leaks at 15 psi.
Pull Test Requirements	No leaks at 5 lbs for small bore and 10 psi for large bore tubing.
Luer Connections	Meets ANSI/HIMA MD70.1-1983 for Medical Materials Luer Taper Fittings.
Package Integrity	Tyvek/Polystyrene tray and Tyvek/Polymylar pouches passed burst test with in accordance with ASTM F1140-88.
Shipping and Distribution Testing	Passed Distribution Simulation Test I/NSTA Project 1A, ASTM D-775-80 and D-999-75.
Accelerated Aging	One (1) year with no effects on performance characteristics.
Heat Exchanger Corrosion Test	Resists corrosion for periods of up to 72 hours.
Air In-line Detection	Detects 100μL size air bubbles in blood and saline.
Hemolytic Characteristics	MPS disposable and instrument lower than predicate devices.
Level Sensing and Autoventing	Meets performance specifications for venting and is equivalent to the predicate device for level sensing
Pressure Control Delivery	Allows greater control of pressure than does the predicate device.

Pressure Alarm Verification	Operates within predicate device's alarm range of 0% to ± 10% of preset value. Allows ability to set lower pressure limits.
Pressure Sensor Accuracy	Equivalent to predicate device specification of ± 5 mmHg.
Pump Performance at Temperature Extremes	MPS has a mean accuracy of 95% of the flow rates (50, 150, 500 ml/minute) delivered at 36°C and 5°C.
Use with Crystalloid Filter	Pressure cuffs allow MPS to provide maximum settable flow rate with the use of a crystalloid filter.
Arrest Agent/Additive Concentration Delivery	Adjustable from 4-40 mEq/L and delivers within ± 10% of desired concentration.
Blood/Crystalloid Ratio Accuracy	Less than 3% of each components required proportion.
Delivery Rate Accuracy	Meets AAMI recommended 5% accuracy specification for infusion pumps.
Pump Output Flow Profile	Depicts a more linear flow rate than the predicate device at 50, 300, 500 ml/minute.
Environmental Tests	Meets temperature, humidity specification requirements and UL External Surface Temperature Safety requirements.
Electrical Safety	Meets UL/CSA requirements for electrical safety.
Temperature Sensor Accuracy	Meets temperature sensor accuracy specifications of 5% of the reading.
Warm and Cold Temperature Control	Heat and cools cardioplegia solution within operating flow rate ranges.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 1 2000

Mr. Malcolm Lewis
Regulatory Affairs Specialist
Quest Medical, Inc.
One Allentown Parkway
Allen, TX 75002-4211

Re: K994274
Trade Name: Quest MPS Perfusion Assisted Direct Coronary Artery Bypass (PADCAB)
Regulatory Class: II (two)
Product Codes: DWK, DTR, DXS, KRL, DRS, and DWF
Dated: March 21, 2000
Received: March 29, 2000

Dear Mr. Lewis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), or 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

STATEMENT OF INTENDED USE FORM

510(K) #: **Not assigned to date**

Device Name: **Quest MPS® Perfusion Assisted Direct Coronary Artery Bypass (PADCAB)**

Indications for Use:

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(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K994274

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **or** **Over-The –Counter Use** ____