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NOV - 6 1997

### **510(k) Summary of Safety and Effectiveness**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**Date Prepared:** May 23, 1997

**Company:** Quest Medical, Inc.  
One Allentown Parkway  
Allen, TX 75002-4211

**Contact:** Krista Oakes, Regulatory Affairs Manager  
**Phone Number:** 972-390-9800  
**Fax Number:** 972-390-2881

**QUEST** Medical, Inc.

ONE ALLENTOWN PARKWAY / ALLEN, TEXAS 75002-4211 / 214 390-9800 / FAX: 214 390-2881

## **Quest Vessel Catheter**

### **510(k) Summary of Safety and Effectiveness**

#### **Device Information:**

Trade Name: Quest Vessel Catheter  
Common Name: Saphenous Vein Cannula  
Classification Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing

#### **Predicate Device:**

DLP Vessel Cannula (Ref. 510(k) # K791832)

#### **Device Description:**

Saphenous vein cannulae are used during cardiopulmonary bypass to test the integrity of vein grafts prior to attachment to the coronary arteries and to facilitate antegrade cardioplegia administration directly down the vein graft following completion of the distal anastomosis.

The harvested vein graft must be tested for leaks or weakened areas prior to attachment to the coronaries to assure a competent conduit. To accomplish this, a small vessel cannula with a tapered shaft is inserted into one end of the graft and secured with a suture. Barbs or bulbous tips on the shaft of the cannula prevent the tied vein from slipping off. The opposite end has a female luer fitting for attachment to a saline-filled syringe. The graft may then be inflated with the saline at low pressures to test for leaks.

The surgeon cuts the graft to a suitable length and proceeds with attachment of the distal anastomosis. When indicated, the surgeon may decide to perfuse cardioplegia through the cannula-graft to the heart using a vein graft perfusion set attached to the cardioplegia delivery line. This allows nourishment to reach those areas of the heart that may not have been well perfused previously due to the arterial occlusion. Furthermore, the surgeon may use the cannula to assess the quality of the distal anastomosis by visual examination under pressure.

#### **Materials:**

- Cannula body: Clear ABS
- Duckbill valve: Silicone

#### **Dimensions:**

- Length: 2.00"
- I.D.: .06"
- O.D. 2nd barb: .16"

Connections: Female luer with taper per ISO 594/1

**Intended Use:**

The Quest Vessel Catheter is intended for use in cardiovascular surgical procedures to test the integrity of vein grafts prior to attachment to coronary arteries, and to facilitate antegrade cardioplegia administration directly down the vein graft following completion of the distal anastomosis.

**Comparison To Predicate Device:**

The following table illustrates the comparison between the modified device and the original, legally marketed device.

|   | <b>DLP (Predicate Device)</b>  | <b>Quest Device</b>  |
|---|--|--|
| <b>Intended Use:</b>  | Facilitate testing and perfusion of vessel during cardiopulmonary bypass | Facilitate testing and perfusion of vessel during cardiopulmonary bypass |
| <b>Design Features:</b>   | Clear body, soft plastic tip, female luer lock, optional duckbill valve  | Clear body, soft plastic tip, female luer lock, optional duckbill valve  |
| <b>Materials:</b><br>• <b>Body</b><br>• <b>Valve</b>                                | PVC<br>Silicone  | Clear ABS<br>Silicone  |
| <b>Dimensions:</b><br>• <b>Length:</b><br>• <b>I.D.:</b><br>• <b>O.D. 2nd barb:</b> | (estimated)<br>2.00"<br>.06"<br>.16"                                     | 2.00"<br>.06"<br>.16"  |
| <b>Packaging:</b>   |  | Tyvek/mylar peel pouch   |
| <b>Labeling:</b>  | Labeled as sterile, non-pyrogenic prescription device                    | Labeled as sterile, non-pyrogenic prescription device                    |
| <b>Expiration Date:</b>   | 3 years  | 1 year   |

**Non-clinical Testing:**Performance Testing

The following laboratory tests were conducted on both the Quest device and the DLP device to demonstrate substantially equivalent performance:

- Pressure drop evaluation
- Leak testing
- Bond strength
- Duckbill valve cracking pressure
- Package integrity

Biocompatibility Testing

Material biocompatibility testing has been performed in accordance with ISO 10993 standards.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Ms. Krista Oakes  
Regulatory Affairs Manager  
Quest Medical, Inc.  
Allentown Parkway  
Allen, Texas 75002-4211

Re: K971928  
Quest Vessel Catheter  
Regulatory Class: II (Two)  
Product Code: DWF  
Dated: September 29, 1997  
Received: September 30, 1997

Dear Ms. Oakes:

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 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.

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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), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 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/dsmamain.html>."

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**STATEMENT OF INTENDED USE FORM**

**510(k) #:** K 971928

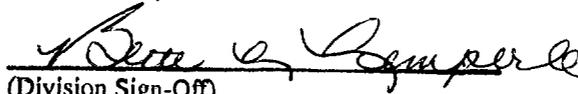
**Device Name:** Quest Vessel Catheter

**Indications for Use:**

The Quest Vessel Catheter is intended for use in cardiovascular surgical procedures to test the integrity of vein grafts prior to attachment to coronary arteries, and to facilitate antegrade cardioplegia administration directly down the vein graft following completion of the distal anastomosis.

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**



(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K 971928

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use