

K964571

AUG 8 1997

510(k) Summary  
SURGIMEDICS®/TMP® Vision Cardioplegia Delivery System  
(per 21 CFR 807.92)

- 1. **Date Prepared:** November 11, 1996
- 2. **Sponsor/Applicant:** SURGIMEDICS® /TMP®  
2828 N. Crescent Ridge Drive  
The Woodlands Research Forest  
The Woodlands, TX 77381
- 3. **Contact Name:** Russell Jones, Manager of Regulatory Affairs  
Telephone Number: 713-363-4949

- 4. **Device Name:**  
  

|                      |                                       |
|----------------------|---------------------------------------|
| Proprietary Name:    | Vision Cardioplegia Delivery System   |
| Common/Usual Name:   | Cardioplegia Heat Exchanger           |
| Classification Name: | Cardiopulmonary Bypass Heat Exchanger |

- 5. **Device Classification:**  
  

Cardioplegia heat exchangers are similar to cardiopulmonary bypass heat exchangers (21 CFR 870.4240, Product Code DTR) which have been classified under Section 513 of the Act as Class II by the Cardiovascular Devices Panel.

- 6. **Predicate Devices:**  
  

The SURGIMEDICS®/TMP® Vision Cardioplegia Delivery System is substantially equivalent to the following legally marketed cardioplegia heat exchangers:

  - Sorin Biomedical Buckberg BCD Vanguard (No K number identified)
  - Sorin Biomedical BCD Advanced Blood Cardioplegia System (K925369)
  - AVECOR Cardiovascular MYOTherm Cardioplegia System (K904171)

**7. Device Description and Substantial Equivalence:**

**Intended Use:** The Vision Cardioplegia Delivery System is intended for mixing, cooling, warming, and delivery of oxygenated blood cardioplegia solution during cardiopulmonary bypass.

**Substantial Equivalence:** The Vision Cardioplegia Delivery System is substantially equivalent to the above listed cardioplegia heat exchangers based on their intended use, design, materials, and principles of operation.

**Operational and Technological Characteristics:** Information provided in this Premarket Notification to support the determination of substantial equivalence for the Vision Cardioplegia Delivery System includes descriptive information about the intended use, operation, and technological characteristics, as well as comparative bench testing which characterizes device performance.

When the performance of the Vision Cardioplegia Delivery System is compared to the Sorin BCD Vanguard Cardioplegia System, the SURGIMEDICS®/TMP®, both devices showed similar rates of hemolysis, heat exchange effectiveness, warming, cooling, internal resistance to flow, maximum water and blood side pressure tolerance, and debubbling capacity.



AUG 8 1997

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

Surgimedics, Inc.  
c/o Ms. Rosina Robinson  
Staff Consultant  
Medical Device Consultants, Inc.  
49 Plain Street  
North Attleboro, Massachusetts 02760

Re: K964571  
Surgimedics®/TMP® Vision Cardioplegia Delivery System (BCD)  
Regulatory Class: II (Two)  
Product Code: 74 DTR  
Dated: June 5, 1997  
Received: June 6, 1997

Dear Ms. Robison:

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 (Pre-market 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 pre-market 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 "dsma@fdadr.cdrh.fda.gov."

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

510(k) Number (if known): K964571

Device Name: Vision Cardioplegia Delivery System

Indications For Use:

The SURGIMEDICS®/TMP® Vision Cardioplegia Delivery System is intended to mix, cool, warm, and deliver oxygenated blood cardioplegia solution during cardiopulmonary bypass.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Ben L. Reynolds*

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

510(k) Number K964571

Prescription Use  X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_