APR 1 0 2002

K020106

Summary

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

1. Company making the submission:

	Company	or	Correspondent (contract):
Name: Address: Telephone: Contact:	Gish BioMedical, Inc. 22942 Arroyo Vista Rancho Santa Margarita, CA 92688-2600 949-635-6240 voice 949-635-6294 fax Edward F. Waddell Director RA/QA		Delphi Consulting Group 11874 South Evelyn Circle Houston, Texas 77071-3404 713-723-4080 voice 208-694-6953 fax harvey@delphiconsulting.com J. Harvey Knauss Consultant

2. Device:

Proprietary Name:	Vision Blood Cardioplegia and Extracorporeal Heat Exchanger
Common Name:	Cardioplegia Heat Exchanger
Classification Name;	Cardiovascular bypass heat exchanger

3. Predicate Devices;

Single pass Cardioplegia, Gish Biomedical, Inc., K896807 & Vanguard and Dideco/Sorin K934763.

4. Classifications Names & Citations:

21 CFR 870.4240, Cardiovascular bypass heat exchanger, Class II, DTR, Cardiovascular.

5. Description:

The Vision Blood Cardioplegia consists of an extracorporeal heat exchanger and fluid administration set. The heat exchanger consists of a one piece, stainless steel bellows, configured heat exchanger as the primary element to affect heat exchange. This element is encased by a polycarbonate housing, which directs the blood through the outside convolutions

of the stainless steel bellows, and therefore effects heat exchange while minimizing priming volume. All materials of the heat exchanger are biocompatible.

The device allows for the monitoring of pressure and allows for trapping and removal of air. Additionally, the device includes an integral bubble trap, gross particulate filter (105 m) and pressure relief device designed to open in the event of excessive fluid pressure (600 mmHg) during use. Solutions are delivered to the patient through the extension line and appropriate cannula. Blood flow is driven by a roller pump connected through the extension line.
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6. Indications for use:

The Vision Blood Cardioplegia is indicated for use in applications that require control of fluid temperature, such as blood or cardioplegia, typically in an extracorporeal circuit. The device may be used for normothermic of hypothermic applications.

7. Contra-indications:

There are no known or reported contraindications for the use of the Vision Blood Cardioplegia.

8. Comparison:

The Vision Blood Cardioplegia device has the same device characteristics as the predicate devices.

9. Test Data:

The Vision Blood Cardioplegia has been subjected to extensive safety, performance, and validations prior to release. Final testing for the systems includes various performance tests designed to ensure that the device meets all of its functional requirements and performance specifications. Safety tests have further been performed to ensure the device complies to applicable industry and safety standards.

10. Literature Review:

A review of literature pertaining to the safety and effectiveness has been conducted. Appropriate safeguards have been incorporated in the design of the Vision Blood Cardioplegia.

11. Conclusions:

The conclusion drawn from these tests is that the Vision Blood Cardioplegia is equivalent in safety and efficacy to its predicated devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2002

GISH Biomedical, Inc.
Mr. James Harvey Knauss
Contract Consultant
c/o Delphi Consulting Group
11874 South Evelyn Circle
Houston, TX 77071

Re: K020106
Trade Name: Vision Blood Cardioplegia System and Extracorporeal Heat Exchanger
Regulation Number: 21 CFR 870.4240
Regulation Name: Cardiopulmonary bypass heat exchanger
Regulatory Class: Class II (two)
Product Code: DTR
Dated: January 8, 2002
Received: January 11, 2002

Dear Mr. Knauss:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
And Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K020106

Device Name: Vision Blood Cardioplegia and Extracorporeal Heat Exchanger

Indications for use:

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Prescription Device: Yes

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020106

(Optional Format 1-2-96)