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:	Gish BioMedical, Inc.		Delphi Consulting Group
Address:	22942 Arroyo Vista Rancho Santa Margarita CA 92688-2600		11874 South Evelyn Circle Houston, TX 77071-3404
Telephone:	949-635-6240 voice 949-635-6294 fax		832-285-9423 voice 832-615-3550 fax
Contact:	Edward F. Waddell Director RA/QA edw@gishbiomedical.com		J. Harvey Knauss Consultant harvey@delphiconsulting.com

2. Device:

Proprietary Name:	Vision Blood Cardioplegia Sytem and Extracorporal Heat Exchanger with GBS™ Coating
Common Name:	Cardioplegia Heat Exchanger
Classification Name:	Cardiopulmonary Bypass heat exchanger

3. Predicate Devices:

   Gish Vision Blood Cardioplegia System and Extracorporal Heat Exchanger, Gish Biomedical, Inc., K020106.

4. Classifications Names & Citations:

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

5. Description:

   The Gish Vision Blood Cardioplegia System with GBS™ coating 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 effect 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 μ) 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 an extension line.

The components of this system which have contact with the fluid path are sterile and nonpyrogenic.

All blood contact materials of the Vision Blood Cardioplegia System with GBS™ coating are biocompatible and coated with a proprietary coating.

6. Indications for use:

   The Gish Vision Blood Cardioplegia System with GBS™ coating 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 or hypothermic applications. It is designed to operate at flow rates of one hundred (100) to six hundred (600) milliliters per minute for periods up to six (6.0) hours.

7. Contraindications:

   For heparin coated devices, heparin has been reported, on rare occasions, to induce thrombocytopenia. Since patients undergoing cardiopulmonary bypass are routinely systemically heparinized, and although the amount of heparin contributed by this device is very small in comparison to the typical dose given, caution should be exercised when using this device in patients with known or suspected heparin sensitivity.

8. Comparison:

   The Gish Vision Blood Cardioplegia System with GBS™ coating has the same device characteristics as the predicate devices.

9. Test Data:

   The Gish Vision Blood Cardioplegia System with GBS™ Coating 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.

10. Special Controls – Section 514 of the ACT

    This submission complies with "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff" and other Guidance and Standards listed in Tab 17.

11. Literature Review:

    A review of literature pertaining to the safety and effectiveness has been conducted. Appropriate safeguards have been incorporated in the design of Gish Vision Blood Cardioplegia System with GBS™ Coating.

12. Conclusions:

    The conclusion drawn from these tests is that Gish Vision Blood Cardioplegia System with GBS™ Coating is equivalent in safety and efficacy to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 5 2004

Gish Biomedical, Inc.
c/o Mr. J. Harvey Knauss
Delphi Consulting Group
11874 South Evelyn Circle
Houston, TX 77071

Re: K040355
Vision Blood Cardioplegia System and Extracorporal Heat Exchanger with GBS™ Coating
Regulation Number: 21 CFR 870.4240
Regulation Name: Cardiopulmonary Bypass Heat Exchanger (Cardioplegia)
Regulatory Class: Class II (two)
Product Code: DTR
Dated: February 10, 2004
Received: Fcbruary 18, 2004

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), 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:	K040355
Device Name:	Vision Blood and Extracorporal Heat Exchanger With GBS™ Coating.
Indications For Use:	The Vision Blood Cardioplegia System with GBS™ coating 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 or hypothermic applications. It is designed to operate at flow rates of one hundred (100) to six hundred (600) milliliters per minute for periods up to six (6.0) hours.

Prescription Use Yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (21 CFR 807 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. Lachman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040355

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