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 775-429-9524 fax harvey@delphiconsulting.com
Contact:	Edward F. Waddell Director RA/QA		J. Harvey Knauss Consultant

2. Device:

Proprietary Name:	IBC FloPump with GBS™ Coating
Common Name:	Centrifugal Pump
Classification Name:	Nonroller-type cardiopulmonary bypass blood pump

3. Predicate Devices:

   IBC FloPump, International Biophysics Corporation, K983272. Pump.
   Vision Hollow Fiber Oxygenator with GBS™ coating, K023381. Coating.

4. Classifications Names & Citations:

5. 21 CFR 870.4360, Nonroller-type cardiopulmonary bypass blood pump, Class III, KFM, Cardiovascular.

6. Description:

   The IBC FloPump with GBS™ Coating (a non leaching heparin based coating) centrifugal blood pump has been designed to utilize the constrained forced-vortex pumping principle. In action, blood is allowed through a vortex created by the rotation of a series of smooth surfaced rotating cones. Energy is transferred from the cones to the blood in the form of pressure and velocity as the blood is gently accelerated toward the outlet of the pump.

   The IBC FloPump with GBS™ Coating centrifugal blood pump is fabricated from sturdy, thromboresistant, biocompatible polycarbonate materials which are mounted on precision bearings for dependable operation. The non-occlusive hemodynamic design of the pump promotes laminar flow, allowing for improved blood handling

capabilities and decreasing trauma which may be associated with extracorporeal circulatory support during cardiopulmonary bypass.

The IBC FloPump with GBS™ Coating centrifugal blood pump couples to a safety-locked magnetic drive unit called the Medtronic Bio-Medicus Bio Console® pump speed controller, which serves as the hardware component of the extracorporeal blood delivery system.

7. Indications for use:

   The IBC FloPump with GBS™ Coating centrifugal blood pump is indicated for use only with the Medtronic Bio-Medicus Bio Console® to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support at flow rates of up to seven (7.0) LPM for periods up to six (6.0) hours.

8. 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.

9. Comparison:

   The IBC FloPump with GBS™ Coating has the same device characteristics as the predicate devices.

10. Test Data:

    The IBC FloPump 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. Safety tests have further been performed to ensure the device complies with applicable industry and safety standards.

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 IBC FloPump with GBS™ Coating.

12. Conclusions:

    The conclusion drawn from these tests is that IBC FloPump with GBS™ Coating 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

MAY 1 4 2003

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

Re: K031300
IBC FloPump with GBS™ Coating
Regulation Number: 21 CFR 870.4360
Regulation Name: Nonroller type cardiopulmonary bypass blood pump
Regulatory Class: Class II (two)
Product Code: KFM
Dated: Undated
Received: April 24, 2003

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. 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 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

510(k) Number K 031300

Device Name: IBC FloPump with GBS™ Coating

Indications for use:

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Prescription Device:

Federal Law (US) restricts this device to sale by or on the order of a physician.

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 _____

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K031300

(Optional Format 1-2-96)