510(k) Summary

Date: June 15, 2005

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:	Gish Biomedical, Inc. 22942 Arroyo Vista Rancho Santa Margarita CA 92688-2600		Delphi Consulting Group 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		J. Harvey Knauss Consultant harvey@delphiconsulting.com

2. **Device:**

Proprietary Name:	Gish CAP35 Reservoir with GBS™ Coating
	Gish CAP35DF Reservoir with GBS™ Coating
	Gish ATR2900 Reservoir with GBS™ Coating
	Gish ATR2900DF Reservoir with GBS™ Coating
Common Name:	Cardiotomy Reservoir
Classification Name:	21 CFR 870.4400 Reservoir, Blood, Cardiopulmonary Bypass

3. **Predicate Devices:**

   Gish ATR2900DF Reservoir
   Gish 35DF Reservoir

4. **Classifications Names & Citations**:

5. 21 CFR 870.4400 Reservoir, Blood, Cardiopulmonary Bypass, Product Code – DTN, Classification Advisory Committee – Cardiovascular.

6. **Description:**

   The ATR2900 Reservoirs and the CAP35 Reservoirs with GBS™ Coating are designed to filter and defoam suctioned blood and remove particulate matter greater than 160 μm (ATR2900 and CAP35) or 20 μm (ATR2900DF and CAP35DF). The integral water seal/water manometer chambers of the ATR2900 and CAP35 series

accommodate pleural drainage applications. The CAP series also includes a CAPVRF version with a 2 stage filter element. One stage is for cardiotomy blood and provides additional filtration over the other stage which is for venous return blood (which is significantly cleaner).

The ATR2900 Reservoirs and the CAP35 Reservoirs with GBS™ Coating may be converted for postoperative use using available accessory Postoperative Conversion Packs.

Each device consists of a blood reservoir and a defoamer/filter cartridge. The blood reservoir container is a polycarbonate housing with sealed lid. The lid includes inlet ports that allow blood into of the defoamer/filter compartments. Additional luer and "quick prime" inlets allow direct addition to the reservoir. The lid also includes over pressurization and excess vacuum relief valves. The defoamer/filter cartridge consists of a cylindrical compartment for filtration of cardiotomy blood as it enters the reservoir.

7. Indications for use:

The Gish ATR2900 Series Reservoirs with GBS™ Coating are indicated for use:

1. During cardiopulmonary bypass surgery to filter and defoam intrathoracic suctioned blood prior to its return to the extracorporeal circuit.

2. During general surgery procedures other than cardiopulmonary bypass, for collection and filtration of suctioned blood. During these procedures, the reservoir must be used in conjunction with appropriate cell-washing techniques.

3. Once intraoperative use is completed, for the collection and autotransfusion of the same patients post operative blood using components available separately in the SVP400 or SVP450 STAT-VAC Conversion Pack, ATR200 or ATR250 Supplemental Drainage Set, ATR500 Wound drainage Postoperative Pack or ATR600 Supplemental Wound Drainage Line Set.

4. With or without a water seal when used for postoperative autotransfusion, depending on user preference and application. The SVP400, SVP450 and STAT-VAC provide a water seal for use with ATR2900. The attending physician is solely responsible for the decision to use or not to use a water seal..

The Gish CAP35 Series Reservoirs with GBS™ Coating with integral water seal/water manometer are indicated for use during cardiopulmonary bypass surgery to filter/defoam intrathoracic suctioned blood prior to its return to the extracorporeal circuit. The CAP35 Series Reservoirs are indicated for the collection and autotransfusion of the same patients postoperative shed blood, using components available separately in the CAP400 or CAP450 Postoperative Conversion Pack and ATR200 or ATR250 Supplemental Drainage Set.

The Gish CAP400/450 Pack is indicated for use exclusively with the Gish CAP Series Products: The Gish CAP400/450 Pack provides components used to convert the Gish CAP systems from intraoperative to post operative use.

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:**

Differences -- None.

10. **Test Data:**

The Gish ATR2900 Reservoirs and the CAP35 Reservoirs with GBS™ Coating have 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.

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 ATR2900 Reservoirs and the CAP35 Reservoirs with GBS™ Coating.

12. **Conclusions**:

The conclusion drawn from these tests is that Gish ATR2900 Reservoirs and the CAP35 Reservoirs with GBS™ Coating are 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

AUG 1 2 2005

Gish Biomedical Inc.
c/o Mr. J. Harvey Knauss
Delphi Consulting Group
11874 South Evelyn Circle
Houston, TX 77071-3404

Re: K051606
Gish ATR2900 and CAP35 Series Reservoirs with GBS™ Coating
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary Bypass Blood Reservoir
Regulatory Class: Class II
Product Code: DTN
Dated: June 15, 2005
Received: June 16, 2005

Dear Mr. Knauss:

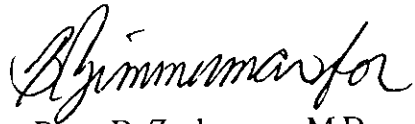
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-0120. 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/industry/support/index.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 051606

Device Name: Gish ATR2900 and CAP35 Series Reservoirs with GBS™ Coating

Indications for use:

The Gish ATR2900 Series Reservoirs with GBS™ Coating are indicated for use:

1. During cardiopulmonary bypass surgery to filter and defoam intrathoracic suctioned blood prior to its return to the extracorporeal circuit.
2. During general surgery procedures other than cardiopulmonary bypass, for collection and filtration of suctioned blood. During these procedures, the reservoir must be used in conjunction with appropriate cell-washing techniques.
3. Once intraoperative use is completed, for the collection and autotransfusion of the same patients post operative blood using components available separately in the SVP400 or SVP450 STAT-VAC Conversion Pack, ATR200 or ATR250 Supplemental Drainage Set, ATR500 Wound drainage Postoperative Pack or ATR600 Supplemental Wound Drainage Line Set.
4. With or without a water seal when used for postoperative autotransfusion, depending on user preference and application. The SVP400, SVP450 and STAT-VAC provide a water seal for use with ATR2900. The attending physician is solely responsible for the decision to use or not to use a water seal..

The Gish CAP35 Series Reservoirs with GBS™ Coating with integral water seal/water manometer are indicated for use during cardiopulmonary bypass surgery to filter/defoam intrathoracic suctioned blood prior to its return to the extracorporeal circuit. The CAP35 Series Reservoirs are indicated for the collection and autotransfusion of the same patients postoperative shed blood, using components available separately in the CAP400 or CAP450 Postoperative Conversion Pack and ATR200 or ATR250 Supplemental Drainage Set.

The Gish CAP400/450 Pack is indicated for use exclusively with the Gish CAP Series Products: The Gish CAP400/450 Pack provides components used to convert the Gish CAP systems from intraoperative to post operative use.

Prescription Device: Yes **OTC** NO

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051606

(Optional Format 1-2-96)