

K030077

510(k) Submission, Tubing and Connectors with GBS™ Coating
Gish Biomedical, Inc., Rancho Santa Margarita, CA 92688

Summary

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

MAR 14 2003

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 | | 713-723-4080 voice 775-429-9524 fax |
| Contact: | Edward F. Waddell Director RA/QA | | harvey@delphiconsulting.com J. Harvey Knauss Consultant |

2. Device:

| | |
|----------------------|---|
| Proprietary Name: | Gish Tubing and Connectors with GBS™ Coating |
| Common Name: | Cardiopulmonary Bypass Tubing and Connectors |
| Classification Name: | Catheter, Cannula or Tubing, Vascular Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting, Cardiopulmonary Bypass |

3. Predicate Devices:

Gish Tubing and Connectors, Gish Biomedical, Inc.

4. Classifications Names & Citations:

21 CFR 870.4210, Catheter, Cannula or Tubing, Vascular Cardiopulmonary Bypass, Class II, DWF, Cardiovascular.

21 CFR 870.4290, Adaptor, Stopcock, Manifold, or Fitting, Cardiopulmonary Bypass, Class II, DTL, Cardiovascular.

5. Description:

The Gish Tubing and Connectors with GBS™ Coating are used in surgical procedures to provide a conduit for extracorporeal blood flow when interconnecting components of the bypass circuit. Specifically they are used in connecting oxygenators, reservoirs, filters, heat exchangers and other devices used in surgical procedures. The tubing is polyvinyl chloride (PVC). The connectors are polycarbonate of various configurations such as straight, "Y", Leur and reducer types.

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

All materials of the Gish Tubing and Connectors are biocompatible and coated with a proprietary coating.

The Gish Tubing and Connectors with GBS™ Coating may be purchased separately or pre-connected with tubing and other components of an extracorporeal circuit

6. Indications for use:

The Gish Tubing and Connectors with GBS™ Coating are indicated for use in surgical procedures to provide a conduit for extracorporeal blood flow when interconnecting components of the bypass circuit. It is designed to operate at flow rates of one (1.0) to six (6.0) liters per minute for periods up to six (6) 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 Tubing and Connectors with GBS™ Coating have the same device characteristics as the predicate devices.

9. Test Data:

The Gish Tubing and Connectors 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. 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 Tubing and Connectors with GBS™ Coating.

11. Conclusions:

The conclusion drawn from these tests is that Gish Tubing and Connectors with GBS™ Coating is equivalent in safety and efficacy to its predicated devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 14 2003

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

Re: K030077

Tubing and Connectors with GBS Coating.

Regulation Number: 21 CFR 870.4290, 870.4210

Regulation Name: Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting
Cardiopulmonary Bypass Vascular Catheter, Cannula and Tubing

Regulatory Class: Class II (two)

Product Code: DTL, DWF

Dated: January 6, 2003

Received: January 8, 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.

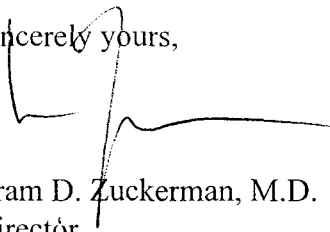
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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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

510(k) Submission, Tubing and Connections with GBS™ Coating
Gish Biomedical, Inc., Rancho Santa Margarita, CA 92688

510(k) Number K030077

Device Name: Gish Tubing and Connectors with GBS™ Coating.

Indications for use:

The Gish Tubing and Connectors with GBS™ Coating are indicated for use in Surgical procedures to provide a conduit for extracorporeal blood flow when interconnecting components of the bypass circuit. It is designed to operate at flow rates of one (1.0) to six (6.0) liters per minute for periods up to six (6) hours.

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

OR

Over-The-Counter Use



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K030077

(Per 21 CFR 801.109)