Summary

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

1. **Company making the submission:**

Name:	GISH Biomedical, Inc. A member of the MEDOS group
Address:	22942 Arroyo Vista Rancho Santa Margarita, CA 92688-2600
Telephone:	949-635-6241 voice 949-635-6299 fax janetp@gishbiomedical.com
Contact:	Janet Peets Regulatory & Clinical Affairs

2. **Device:**

Proprietary Name:	MEDOS HILITE 7000 & 7000 LT Hollow Fiber Oxygenator
Common Name:	Blood Oxygenator
Classification Name:	Oxygenator, Cardiopulmonary Bypass

3. **Predicate Devices:**
Vision Hollow Fiber Oxygenator, K961530, Manufactured by GISH Biomedical, Inc.

4. **Classifications Names & Citations:**
21 CFR 870.4350, Oxygenator, Cardiopulmonary Bypass, Class II, DTZ, Cardiovascular.

5. **Description:**
The MEDOS HILITE 7000 & 7000 LT Oxygenator consists of a hollow fiber membrane oxygenator and extracorporeal heat exchanger. The MEDOS HILITE 7000 hollow fiber membrane consists of a polypropylene gas permeable mat. The MEDOS HILITE 7000 LT hollow fiber membrane consists of a Polymethylpentene plasma tight mat. The unique mat design increases the interaction between blood and gas, creating a highly efficient blood oxygenator. The heat exchanger consists of a polyester non-porous hollow fiber configured heat exchanger as the primary element to effect heat exchange. This element is encased by a polycarbonate housing, which directs the blood around the outside of the fibers while water flows through the inner lumen of the fibers and therefore effects heat exchange while minimizing priming volume. All materials of the heat exchanger are biocompatible and coated with a proprietary coating. The device allows for trapping and removal of air. Oxygenated blood is delivered to the patient through the tubing and appropriate cannula. Blood flow is driven by a roller pump or centrifugal pump connected through the tubing. The MEDOS HILITE 7000 Oxygenator may be purchased separately or pre-connected with tubing and other components of an extracorporeal circuit.

6. **Indications for use:**
   The MEDOS HILITE 7000 & 7000 LT Hollow Fiber Oxygenator is indicated for use in procedures requiring the extracorporeal oxygenation of and carbon dioxide removal from human blood. It is designed to operate at a blood flow rate of one (1.0) to seven (7.0) liters per minute for periods of up to six (6.0) hours.

7. **Contra-indications:**
   For oxygenators, no contra-indications have been noted.

8. **Comparison:**
   The MEDOS HILITE 7000 & 7000 LT Oxygenator has the same device characteristics as the Predicate device.

9. **Test Data:**
   The MEDOS HILITE 7000 & 7000 LT Oxygenator 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.

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 MEDOS HILITE 7000 & 7000 LT Oxygenator.

11. **Conclusions:**
    Based upon the testing and comparison to the predicate device the MEDOS HILITE 7000 & 7000 LT Hollow Fiber Oxygenator has the same intended use, with similar technological characteristics. GISH Biomedical, Inc. a member of the MEDOS group, therefore posits that its device is equivalent in safety and effectiveness to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2009

Gish Biomedical, Inc.
c/o Ms. Janet Peets
Regulatory & Clinical Affairs Specialist
22942 Arroyo Vista
Rancho Santa Margarita, CA 92688

Re: K082403
MEDOS HILITE 7000 & 7000 LT Hollow Fiber Oxygenator
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: May 1, 2009
Received: May 5, 2009

Dear Ms. Peets:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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 **K082403**

Device Name: MEDOS Hilite 7000 & 7000 LT Oxygenator

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.

Prescription Use : Yes OR Over-The-Counter Use: No

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vickers

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082403