JUN 2 3 2003

K 031150

510(k) SUMMARY

The HEMOBAG™ Blood Salvage Device is a storage reservoir for blood that can be held, circulated and hemoconcentrated. It is designed for use in salvaging anticoagulated whole blood from extracorporeal circuits. When used in conjunction with a TS3 Tubing Set and a commercially available hemoconcentrator, the HEMOBAG™ serves as a hemoconcentrating reservoir for use in a closed circuit recovery loop for removal of excess plasma water and low molecular weight solutes. The richly concentrated, anticoagulated, autologous whole blood is then quickly made available to the patient for gravity transfusion.

The HEMOBAG™ is designed with a universal (1/4" – 3/8") stepped connector on the arterial infusion port to allow lines of varying sizes to be attached to the bag. The inlet and outlet ports of the bag are designed with quick connect/disconnect ¼" connectors to mate with the TS3 Tubing set for fluid delivery to and from the hemoconcentrator. The HEMOBAG™ is equipped with a needleless port for ease of access. The HEMOBAG™ has been designed with a spike port to facilitate gravity transfusion. A baffle has been positioned inside the bag to allow the blood from the hemoconcentrator to enter the bag and circulate toward the top of the bag and down again to the outlet port allowing proper mixing and flow during hemoconcentration.

SAFETY TESTING

The sterile HEMOBAG™ was subjected to biological evaluation (biocompatibility testing) using the guidelines provided in ANSI/AAMI/ISO 10993, Vol. 4 for limited exposure medical devices that have contact with circulating blood. The device successfully passed all of these tests.

The HEMOBAG™ was evaluated to determine whether or not it introduced more trauma to the blood than the predicate device. The evaluation was done by determining the cellular depletion and hemolysis of anticoagulated bovine whole blood that had been circulated through the HEMOBAG™ at a rate of approximately 1.2 liters per minute for a 1-hour period. An identical evaluation was performed on the anticoagulated bovine whole blood that had been circulated through the predicate device in the same manner. The results of these tests proved that the difference between the amount of cellular damage noted in the blood that had been circulated through the HEMOBAG™ and that which had been circulated through the predicate device was statistically insignificant. Cellular damage was measured by change in hematocrit, platelet depletion, white blood cell count, plasma free hemoglobin and calculated % hemolysis. Blood in the test circuits was evaluated and found to have demonstrated acceptable hematological parameters during the test period. Since the test parameters used represent a scenario that is far worse than parameters that will be seen in proper clinical use, this device is considered safe with respect to cellular damage and hemolysis when used under abnormal stressful conditions.

EFFECTIVENESS

The function and purpose of this device is to accommodate and hold up to 2000ml of anticoagulated whole blood salvaged from an extracorporeal circuit after the patient has been removed. The device also functions as a reservoir for the same blood as it is hemoconcentrated by ultrafiltration for ultimate gravity transfusion to the patient. The HEMOBAG™ has been designed using materials and processes that will allow the flexible bag to hold up to 2000ml of fluid circulating at a rate of 300 – 500ml per minute for a period of approximately 10 – 15 minutes. The functionality of the HEMOBAG™ was successfully tested by overfilling the bag with warm water by 10 – 20% and allowing the bag to hang for a period of 2 hours and then water to circulate through the bag at a rate of 2000 ml per minute for a period of 2 hours. Since the test parameters used represent a scenario far worse than those seen in clinical use, the device is considered effective with respect to its ability to serve as a reservoir for holding, circulating and hemoconcentrating up to 2000ml of anticoagulated whole blood. The rounded corners and baffle inside the bag allow mixing and proper flow of the blood through the HEMOBAG™ during hemoconcentration.

APPENDIX D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2003

Global Blood Resources, LLC
Mr. Keith Samolyk, CCP
President & CEO
998 Windsor Avenue
Windsor, CT 06096

Re: K031150
Trade/Device Name: HEMOBAG™
Regulation Number: 21 CFR 870.4400
Regulation Name: Blood Reservoir
Regulatory Class: Class II (two)
Product Code: DTN
Dated: April 7, 2003
Received: April 10, 2003

Dear Mr. Samolyk:

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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

JUN 2 3 2003

INTENDED USE

The HEMOBAG™ is a blood circulating storage reservoir designed to collect anticoagulated whole blood salvaged from extracorporeal circuits after the patient has been disconnected from the circuit. When used in connection with the TS3 Tubing Set and a commercially available hemoconcentrator, the HEMOBAG™ serves as a reservoir for circulating and hemoconcentrating blood in a closed circuit recovery loop.

C M Yoder for B. Buckman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031150