K022167

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Attachment 7

510(k) SUMMARY

PALL's DONOR® Pre-evacuated Post-Operative Autologous Blood Transfusion System

Submitter's Name, Address, Telephone Number, Contact Personand Date Prepared

Pall Medical
2200 Northern Boulevard
East Hills, NY 11548
Phone: 516-484-5400
Fax: 516-801-9059

Contact Person: Leonard S. Berman, Ph.D.

Date Prepared: June 28,2002]

Name of Device

Pall Donor ® Pre-evacuated Post-Operative Autologous Blood Reinfusion System

Common or Usual Name: Autotransfusor

Classification Name: Autotransfusion Apparatus

Predicate Devices:

- Zimmer Hemovac
- Gish Biomedical, Inc.'s Orthofusor Wound Drainage/Autotransfusion System
- Richards' Solocotrans
- Stryker Surgical's CBC-ConstaVac®

Intended Use / Indications for Use

The DONOR. HemoVac, Orthofusor, Solocotrans, and ConstaVac are intended to be use to collect, filter, and reinfuse blood lost by the patient due to surgery. They are indicated for the post-operative collection of blood from an orthopedic surgery patient's wounds and body cavities, filtration of that blood, and reinfusion of the blood into the same patient. Thus, the DONOR has the same intended use and general indications as its predicate devices.

In addition, The DONOR significantly reduces lipids, leucocytes, and C3a from the blood before reinfusing it. The 510(k) notice includes bench data that substantiates each of these claims.

Performance Data

The Donor was tested in accordance with ANSI/AAMI/AT-6 (1991) and found to comply with that standard. Bench data substantiates the DONOR's leukocyte, lipid, and C3a reduction claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 7 2003

Pall Corporation
c/o Leonard S. Berman, Ph.D.
Director of Scientific Affairs
2200 Northern Boulevard
East Hills, NY 11548

Re: K022167
Trade Name: Pall Donor® Pre-evacuated Post-Operative Autologous Blood
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II (two)
Product Code: CAC
Dated: December 15, 2002
Received: December 17, 2002

Dear Dr. Berman:

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,

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

Enclosure

PALL Medical

Attachment 8

Indications for Use Statement

510(k) Number (if known): K022167

Device Name: Pall Donor ® Pre-evacuated Post-Operative Autologous Blood Reinfusion System

Indications for Use: Pall Donor ® Pre-evacuated Post-Operative Autologous Blood Reinfusion System is indicated for the post-operative collection of blood from an orthopedic surgery patient's wounds and body cavities, filtration of that blood, and reinfusion of the blood into the same patient. Pall Donor ® Pre-evacuated Post-Operative Autologous Blood Reinfusion System significantly reduces lipids, leucocytes, and C3a from the blood before reinfusing it.

(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 K022167

Prescription Use X OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

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