510(k) Summary

Applicant: Blood Product Specialties LLC
Address 65 Commerce Way
Hackensack, NJ 07601

Contact Person: Alan A. Waldman, Ph.D.
Waldman Biomedical Consultancy
Address P.O. Box 575
Oceanside, NY 11572
Telephone (516) 763-1158
FAX (516) 536-7628
Email draaw@aol.com

Submission Correspondent: Jane Campbell
Telephone (845) 469-4289
FAX (845) 469-4212
Email jdca@optonline.net

Device Information:

Trade Name: These devices will be marketed under the trade name Pedi-Syringe Filter™ in either 30 mL or 60 mL size

Common/Usual Name: Fluid reservoir and delivery system

Classification Name: The classification name which most closely describes these devices is "Set, Blood Transfusion"

Establishment Registration Number: 2248588

Class: II

Panel: 80

Product code: BRZ

Predicate Device: Charter Medical Neonatal Syringe Set (K000685)

Device Description: Tubing assembly with a 150 micron filter connected by tubing to a spike at one end and connected by tubing to a piston syringe at the other end. Between the filter and the spike there is a clamp.

Intended Use: Intended to prepare and deliver small aliquots of filtered whole blood, red blood cells, platelets plasma and cryoprecipitate for pediatric and/or neonatal transfusion.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 2005

Blood Products Specialties LLC
C/O Alan A. Waldman, Ph.D.
Waldman Biomedical Consultancy, Incorporated
184 Seiffert Court
Oceanside, New York 11572

Re: K050805
Trade/Device Name: Pedi-Syringe Filter™
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: BRZ, FMF
Dated: March 29, 2005
Received: March 30, 2005

Dear Dr. Waldman:

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) 276-0115. 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050805

Indications For Use

510(k) Number (if known): K050805

Device Name: Pedi-Syringe Filter™

Indications For Use: Blood Product Specialties Pedi-Syringe Filter™ is intended to prepare and deliver small aliquots of filtered whole blood, red blood cells, platelets, plasma and cryoprecipitate for pediatric and/or neonatal transfusion.

Prescription Use ✓ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050805