K023141

JAN 16 2003

510(k) Summary
Standard Human Plasma

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer:	Contact Information:
Dade Behring Marburg GmbH Emil-von-Behring Str. 76 Marburg/Germany	Dade Behring Inc. Glasgow Site P.O. Box 6101 Newark, Delaware 19714 Attn: Donna Wolf Tel: 302-631-0384
Preparation date:	September 19, 2002

2. Device Name/ Classification:

Standard Human Plasma / Multipurpose system for in vitro coagulation studies (864.5425)

3. Identification of the Legally Marketed Device:

Standard Human Plasma (K924393)

4. Device Description:

Standard Human Plasma is a lyophilized calibrator prepared from pooled citrated human plasma, stabilized with buffer solution and then lyophilized. It is assayed for the calibration of various coagulation and fibrinolysis tests

5. Device Intended Use:

For the calibration of the following tests: Prothrombin time (PT), Fibrinogen, Coagulation factors II, V, VII, VIII, vWF, IX, X, XI, XII and XIII*, Inhibitors: Antithrombin III, Protein C, Protein S, α2-antiplasmin, C1-inhibitor*, Total complement activity*, Plasminogen. (* Not available in the U.S.)

6. Medical device to which equivalence is claimed and comparison information:

Standard Human Plasma (modified) is substantially equivalent in intended use to the Standard Human Plasma (K924393) currently marketed. Standard Human Plasma (modified), like the current Standard Human Plasma is intended for the calibration of coagulation and fibrinolysis tests using a variety of mechanical and photo-optical coagulation systems.

7. Device Performance Characteristics:

Stability:
In duplicate determinations, reconstituted stability data met the acceptance criteria of recovering within the assigned values for the following claims: 4 hours at +15 to +25°C, 4 weeks at -20 to -30°C (2 hours after thawing at +15 to +25°C, stored for 4 weeks at -20 to -30°C.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Donna Wolf
Senior Regulatory Affairs Specialist
Dade Behring, Inc.
Glasgow Site
P.O. Box 6101
Newark, Delaware 19714

JAN 16 2003

Re: k023141
Trade/Device Name: Standard Human Plasma
Regulation Number: 21 CFR § 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: II
Product Code: JPA
Dated: December 17, 2002
Received: December 18, 2002

Dear Ms. Wolf:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Device Name: Standard Human Plasma

Indications for Use:

For the calibration of the following tests:
1. Prothrombin time (PT)
2. Fibrinogen
3. Coagulation factors II, V, VII, VIII, wWf, IX, X, XI, XII and XIII*
4. Inhibitors: Antithrombin III, Protein C, Protein S, α2-antiplasmin, C1-inhibitor*
5. Total complement activity*
6. Plasminogen

* Not available in the U.S.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Over-The-Counter-Use _____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023141