JUN 21 2002

K020980

Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name: George M. Plummer
Dade Behring, Inc.
Building 500, Mailbox 514
P.O. Box 6101
Newark, DE 19714-6101
Phone: (302) 631-9798
FAX: (302) 631-6299

Date of Preparation: 3/18/02

Device Name: Total Prostate Specific Antigen Calibrator

Classification Name: Calibrator, secondary

Predicate Device: PSA Calibrator for Dimension® clinical chemistry system (K973100)

Device Description: The Total PSA Calibrator is a five-level product. Levels 1,2,4,5, and 6 contain 0.0, 4.0, 20.0, 50.0, and 108.0 ng/mL PSA, respectively. Level 1 is a horse serum base with no detectable PSA. Levels 2,4,5 and 6 contain a human prostate specific antigen (free PSA) in a bovine serum albumin base. Bottle values are assigned according to the process outlined in Appendix B. Level 3 is reserved for use with future methods and will not be included in the packaging at this time.

Intended Use: The TPSA Calibrator is an *in vitro* diagnostic product intended to be used to calibrate the Total Prostate Specific Antigen method for the Dimension® clinical chemistry system with the heterogeneous immunoassay module. This product was designed to meet the needs of users to assure accurate results over the assay range of this method.

Comparison to Predicate Device:

	PSA Calibrator for Dimension®	Total Prostate Specific Antigen Calibrator for Dimension®
Intended Use	Calibrator	Calibrator
Analyte	Human PSA	Human PSA
Matrix	Level 1 Horse Serum Level 2-5 BSA	Level 1 Horse Serum Level 2,4,5,6 BSA
Form/Storage	Frozen (-10°C to -20°C)	Liquid (2°C to 8°C)
Values	Assigned	Assigned
Levels	5 levels	5 levels
Packaging Configuration	1.0 mL	2.0 mL vials, 10 vials per kit, 2 vials at each level

Comments on Substantial Equivalence: The Total Prostate Specific Antigen Calibrator for the Dimension® clinical chemistry system is equivalent to the PSA Calibrator for the Dimension®. Both products contain human Prostate Specific Antigen as the analyte source and are for use as calibrators for Prostate Specific Antigen Assays.

Conclusion: The Total Prostate Specific Antigen Calibrator for the Dimension® clinical chemistry system is substantially equivalent to the PSA Calibrator for the Dimension® based on the comparison summarized above.

George M. Plummer
Regulatory Assurance and
Compliance Manager
Date: March 18, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. George M. Plummer
Regulatory Assurance and Compliance Manager
Dade Behring, Inc.
Building 500, Mailbox 514
P.O. Box 6101
Newark, Delaware 19714-6101

JUN 21 2002

Re: k020980
Trade/Device Name: Total Prostate Specific Antigen Calibrator
Regulation Number: 21 CFR § 862.1150
Regulation Name: Calibrator, Secondary
Regulatory Class: II
Product Code: JIT
Dated: June 11, 2002
Received: June 18, 2002

Dear Mr. Plummer:

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 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. 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 807.97). 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

K020980

Device Name: Total Prostate Specific Antigen Calibrator

Indications for Use:
The TPSA Calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens.

George M. Plummer
Regulatory Assurance and
Compliance Manager
March 18, 2002

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___√___ OR Over-The-Counter Use _____
(Per 21 CRF 801.109)

(Optional Format 1-2-96)

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