K973100

DADE

SEP 29 1997

DADE INTERNATIONAL

Chemistry Systems
P.O. Box 6101
Newark, DE 19714

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: Rebecca S. Ayash
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Building 500, Mailbox 514
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: 8/15/97

Device Name: Prostate Specific Antigen (PSA) Calibrator

Classification Name: Calibrator, Secondary

Predicate Device: aca® plus Prostate Specific Antigen Calibrator

Device Description: Prostate Specific Antigen (PSA) Calibrator for the Dimension® RxL clinical chemistry system with the heterogeneous immunoassay module is a frozen product. The Level 1 calibrator is horse serum based with no detectable PSA. Levels 2 through 5 contain human PSA-ACT in a bovine serum albumin base. The kit consists of ten vials; two at each of five levels, containing 1 mL each.

Intended Use: PSA Calibrator is intended to be used to calibrate the PSA method for the Dimension® RxL clinical chemistry system with the heterogeneous immunoassay module.

Comparison to Predicate Device:

	Dimension® RxL PSA Calibrator	aca® plus PSA Calibrator
Intended Use	Calibrator	Calibrator
Analyte	PSA-ACT	PSA-ACT
Matrix	L-1 horse serum L-2-5 BSA	L-1 horse serum L-2-3 BSA
Form	frozen	liquid
Volume	1.0 mL per vial	3.0 mL per vial
Levels	5 levels	3 levels

Comments on Substantial Equivalence: Both the PSA Calibrator for the Dimension® RxL system and the aca® plus PSA Calibrator are manufactured using the same matrices and contain PSA-ACT as the analyte source. Both products are intended to be used as calibrators for prostate specific antigen assays.

Conclusion: PSA Calibrator for the Dimension® RxL system is substantially equivalent to the aca® plus PSA Calibrator based on the comparison summarized above.

Rebecca S. Ayash
Regulatory Affairs and
Compliance Manager
Date: 8/15/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Rebecca S. Ayash
Regulatory Affairs and Compliance Manager
Dade International Inc.
Building 500, mailbox 514
P.O. Box 6101
Newark, DE 19714-6101

SEP 29 1997

Re: K973100
Trade Name: Prostate Specific Antigen (PSA) Calibrator
Regulatory Class: II
Product Code: JIT
Dated: August 15, 1997
Received: August 19, 1997

Dear Ms. Ayash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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 Statement

Device Name: Prostate Specific Antigen (PSA) Calibrator

Indications for Use: The PSA Calibrator is an *in vitro* diagnostic product intended to be used to calibrate the Prostate Specific Antigen (PSA) method for the Dimension® RxL 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.

Rebecca S. Ayash
Regulatory Affairs and
Compliance Manager
Date: 9/25/97

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K 973100
510(k) Number

Victor E. Mosher
Division Sign-Off
Office of Device Evaluation

Prescription Use ✓