K973101

DADE

DADE INTERNATIONAL

Chemistry Systems
P.O. Box 6101
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SEP 18 1997

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:

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Date of Preparation: 8/15/97

Device Name: Prostate Specific Antigen (PSA) Method

Classification Name: Prostate Specific Antigen for Management of Prostate Cancer

Predicate Device: aca® plus PSA Test Kit

Device Description: The PSA method is a one-step enzyme immunoassay. Sample is incubated with chromium dioxide particles (CrO_2) coated with monoclonal antibodies specific for a binding site on the PSA molecule and conjugate reagent [β-galactosidase (β-gal) labeled monoclonal antibodies specific for a second binding site on the PSA molecule] to form a particle/PSA/conjugate sandwich. Unbound conjugate and analyte are removed by magnetic separation and washing. The sandwich bound β-gal catalyzes the hydrolysis of chlorophenol red-β-d galactopyranoside (CPRG) to chlorophenol red (CPR). The color change measured at 577nm due to the formation of CPR is directly proportional to the concentration of PSA present in the patient sample.

Intended Use: The PSA method is used on the Dimension® RxL clinical chemistry system with the heterogeneous immunoassay module to quantitatively measure PSA in human serum and plasma. Measurements of PSA aid in the management of prostate cancer patients.

Comparison to Predicate Device:

Item	Dimension® RxL PSA	aca® plus PSA
Technology	Sandwich format monoclonal antibody immunoassay	Sandwich format monoclonal antibody immunoassay
Detection	Colorimetric rate measurement at 577nm and 700nm	Colorimetric endpoint measurement at 577nm and 600nm
Specimen type	serum	serum
Sample Size	40µL	100µL

Comments on Substantial Equivalence: Split sample comparison between the PSA method on the Dimension® RxL clinical chemistry system and the aca® plus PSA Test Kit gave a correlation coefficient of 0.994, slope of 1.06 ± 0.01 and an intercept of -0.07 ± 0.14 ng/mL when tested with 596 clinical patient samples ranging from 0.00 to 99.9 ng/mL. The Dimension® RxL assay compared well with the aca® plus assay in all healthy and disease state categories. Data obtained were consistent with the clinical status of the patient.

Conclusion: The PSA method for the Dimension® RxL system with the heterogeneous immunoassay module is substantially equivalent in principle and performance to the aca® plus PSA Test Kit based on the split sample comparison summarized above.

Rebecca S. Ayash

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

Ms. Rebecca S. Ayash
Regulatory Affairs and
Compliance Manager
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Newark, Delaware 19714-6101

SEP 18 1997

Re: K973101
Trade Name: Prostate Specific Antigen (PSA) Method
Regulatory Class: II
Product Code: LTJ
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) Method

Indications for Use: The PSA method for the Dimension® RxL with the heterogeneous immunoassay module is a device used to measure PSA in serum as an aid in the management of prostate cancer patients.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maxim

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

K973101
510(k) Number

Division Sign-Off
Office of Device Evaluation

Prescription Use ✓