K974816

Summary of Safety and Effectiveness

FEB 20 1998

Prepared December 19, 1997

K974816

1. General Information

Device Generic Name:	Prostate Specific Antigen (PSA) Immunological Test System for Management of Prostate Cancers
Device Trade Name:	ACCESS® PSA Assay
Applicant's Name and Address:	Beckman Instruments, Inc. 1000 Lake Hazeltine Drive Chaska, MN 55318
Contact Person:	Ellen Voss, M.S.

2. Predicate Device

Tandem®-R PSA Immunoradiometric Assay
Hybritech, Inc.
P. O. Box 269006
San Diego, CA 92196-9006

PMA Number: P850048

3. Device Description

The ACCESS® PSA Immunoassay Reagents and the ACCESS® Immunoassay Analyzer comprise the ACCESS® Immunoassay System for the quantitative determination of PSA in human serum.

4. Indications for Use

The ACCESS® PSA Immunoassay is a paramagnetic particle chemiluminescent immunoassay for the quantitative determination of prostate-specific antigen (PSA) in human serum using the ACCESS® Immunoassay System. PSA, measured by the ACCESS® PSA Immunoassay, is intended for use as an aid in the management of patients with prostate cancer.

5. Comparison of Technological Characteristics

Both the ACCESS® PSA Immunoassay and the Tandem®-R PSA assay quantitatively measure serum PSA by means of simultaneous immunoassays utilizing the binding of PSA to monoclonal antibodies specific to similar epitopes on the PSA molecule. Both systems measure complexed and free forms of PSA equally. Both systems utilize liquid multi-point calibrators.

The ACCESS® PSA Immunoassay Reagents are designed for use on the ACCESS® Immunoassay Analyzer, a fully automated, random access system, while the Tandem®-R PSA assay is a manual method. The ACCESS® Immunoassay Analyzer uses magnetic particle solid phase enzyme immunoassays with chemiluminescent measurement, while the Tandem®-R PSA assay uses a plastic bead solid support with radioactive labeling and detection. The ACCESS® Immunoassay Analyzer stores reagents on board for up to 24 different analytes and has 28 day calibration curve stability, while Tandem®-R PSA assay is an individual analyte reagent kit requiring a new calibration with each assay.

6. Summary of Studies

Correlation: A comparison of PSA values from 293 samples, ranging from 0.0 to 150.0 ng/ml, run with both the ACCESS® PSA Immunoassay and the Tandem®-R PSA assay

demonstrated very good agreement with the following statistical data:
r = 0.994; y = 1.01x - 0.96.

Expected Range: In a population of apparently healthy males, 97.5% had PSA values of 4.0 ng/ml or less, with the remaining 2.5% having values in the 4 to 10 ng/ml range.

Monitoring Data: 127 monitoring samples (4 to 6 longitudinal samples per patient) from a total of twenty-nine (29) previously diagnosed prostate cancer patients were compared on the ACCESS® PSA and Tandem®-R PSA assays to verify the intended use claim for monitoring. The data demonstrate that the ACCESS® PSA results were highly concordant to both the Tandem®-R PSA results and the concurrent clinical assessment or predicted the subsequent clinical assessment.

Recovery: Linearity studies performed by diluting human serum samples with ACCESS® PSA Sample Diluent provided an average recovery of 98.4%, with individual recoveries ranging from 94.9 to 105.4%. Recovery of exogenous PSA spiked into serum samples resulted in an average recovery of 99.0%, with individual recoveries ranging from 95.2 to 104%.

Precision: Intra-assay imprecision ranged from 1.29% CV to 2.35% CV. Inter-assay imprecision ranged from 1.33% CV to 3.10% CV. Total impression was less than 5% at PSA levels ranging from 0.32 to 81.58 ng/ml.

Specificity: There was no significant interference from potential sample contaminants (albumin, bilirubin, HAMA, hemoglobin, PAP and triglycerides) or therapeutic drugs (acetamidophenol, acetylsalicyclic acid, cisplatin, cyclophosphamide acid, doxorubicin, methotrexate, phenacetin, and vinblastin).

Analytical Sensitivity: The lowest detectable level of PSA distinguishable from zero (ACCESS® PSA Calibrator S0) with 95% confidence is 0.013 ng/ml.

7. Conclusion

The ACCESS® PSA Immunoassay Reagents, when used in conjunction with the ACCESS® Immunoassay Analyzer, are substantially equivalent to the Tandem®-R PSA test system. The ACCESS® PSA Immunoassay is appropriate for monitoring patients with prostate cancer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Ellen Voss, M.S.
Clinical and Regulatory Associate
Beckman Instruments, Inc.
Immunodiagnostic Development Center
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318-1084

FEB 20 1998

Re: K974816
Trade Name: ACCESS® PSA Assay
Regulatory Class: II
Product Code: LTJ
Dated: December 18, 1997
Received: December 23, 1997

Dear Ms. Voss:

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 FOR USE STATEMENT

510(k) Number (if known):K974816

Device Name: ACCESS® PSA

Indications For Use:

The ACCESS® PSA assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of prostate-specific antigen (PSA) in human serum using the ACCESS Immunoassay System. PSA measured by the ACCESS PSA Immunoassay, is used as an aid in the management of patients with prostate cancer.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Maker

(Division Sign-Off)
Division of Clinical Laboratory Devices K974816
510(k) Number

Prescription Use ✓ OR Over-The Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)