K964595

JUN 24 1997

510(k) Summary for OPUS PSA

1. Manufactures Name, Address, Telephone, and contact person, date of preparation:

Manufacturer:	Behring Diagnostics Inc. 151 University Avenue Westwood, MA 02090 617-320-3023 Attn: Kathleen Dray-Lyons
Preparation date:	March 10, 1996

2. Device Name/ Classification:

OPUS PSA:	Tumor Associated Antigen Immunological Test
Classification Number:	class II (classification number has not been assigned)

3. Identification of the legally marketed device:

Hybritech Tandem-E PSA

4. Proposed Device Description:

OPUS PSA is a set of reagents intended to be used together with the OPUS immunoassay analyzers for the quantitative measurement of prostate specific antigen (PSA) in human serum.

5. Proposed Device Intended Use:

OPUS PSA is an *in vitro* fluorogenic enzyme immunoassay (ELISA) for the quantitative measurement of prostate specific antigen (PSA) in serum. OPUS PSA is an adjunctive test used as an aid in the monitoring of prostate cancer patients. OPUS PSA is intended for use with the OPUS analyzers.

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

The OPUS PSA assay is substantially equivalent in intended use to results obtained using the Hybritech Tandem-E PSA. The Hybritech Tandem-E PSA, like the proposed product, employs the principle of two site or sandwich immunoassay. Both use a labeled antibody for the quantitative measurement of PSA in human serum. The OPUS PSA and the Hybritech Tandem-E PSA are based on a six level calibrator system.

The OPUS PSA differs from the Hybritech Tandem-E PSA in that the enzyme labeled antibody is a mouse monoclonal in the Hybritech Tandem-E PSA, while the enzyme labeled antibody is a goat polyclonal in the OPUS PSA test. Also, the OPUS PSA includes a tri-level control, where as the Hybritech Tandem-E PSA test includes a bi-level control. Also, the Hybritech Tandem-E PSA is intended as an aid in the detection of prostate cancer as well as an aid in management of patients with prostate cancer, while the OPUS PSA is only intended for the management of patients with prostate cancer.

7. Proposed Device Performance Characteristics:

Precision

Intra-assay precision was determined by the evaluation of three levels of control material in replicates of twenty (20) each. %CV ranged from 5.1 to 5.8

Inter-assay precision was determined by the evaluation of three levels of control material in duplicate, assayed over a ten day period to total 40 replicates. %CV ranged from 6.6 to 7.0

Accuracy by Recovery

Recovery was determined by making four dilutions of an elevated PSA patient sample into a normal human serum pool. The samples were assayed using OPUS PSA in replicates of three. Percent recovery ranged from 97 to 107%

Accuracy by Correlation

OPUS PSA was compared to a commercially available immunoassay by evaluation of 145 serum samples ranging from 0.443 to 90.7 ng/ml. A correlation coefficient of 0.98 was obtained with a y-intercept value of 0.36 and a slope of 0.94.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 24 1997

Kathleen Dray-Lyons
Manager, Regulatory Affairs
Behring Diagnostics, Inc.
151 University Avenue
Westwood, MA 02090

Re: K964595/S001
Trade Name: OPUS PSA Test
Regulatory Class: II
Product Code: LTJ
Dated: March 25, 1997
Received: March 26, 1997

Dear Ms. Dray-Lyons:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

Behring Diagnostics Inc.
OPUS® PSA
510(k) Notification

510(k) Number (if known): K964595

Device Name: OPUS PSA Test System

Indications For Use:

OPUS PSA is an *in vitro* fluorogenic enzyme immunoassay (ELISA) for the quantitative measurement of prostate specific antigen (PSA) in serum. OPUS PSA is an adjunctive test used as an aid in the monitoring of prostate cancer patients. OPUS PSA is intended for use with the OPUS analyzers.

Peter E. Maheri

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K964595

(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 CFR 801.109)

(Optional Format 1-2-96)