K031343

MAY 15 2003

Summary of Safety and Effectiveness Information

This safety and effectiveness summary 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.
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: April 25, 2003

Name of Product: TPSA Flex® Reagent Cartridge

FDA Classification Name: Total Prostate Specific Antigen for the detection and management of prostate cancer

Predicate Device: Dade Behring TPSA Flex® reagent cartridge (P000021/S2)

Intended Use: The TPSA method for the Dimension® clinical chemistry system with the heterogeneous immunoassay module is an *in vitro* diagnostic test intended to quantitatively measure total prostate specific antigen (PSA) in human serum and plasma:

1. as an aid in the detection of prostate cancer when used in conjunction with digital rectal exam (DRE) in men 50 years or older. Prostate biopsy is required for diagnosis of cancer
2. as an aid in management (monitoring) of prostate cancer patients.

Comparison to Predicate Device:

The TPSA Flex® reagent cartridge with the labeling revision referenced in this submission is substantially equivalent in intended use, principle and performance to the current Dade Behring Total Prostate Specific Antigen assay (P000021/S2). Both assays are *in vitro* immunoassays with intended uses for the measurement of Prostate Specific Antigen in serum and plasma.

There are no formulation or design changes associated with this labeling change. The two products are identical and use the same manufacturing processes. When the TPSA Flex® reagent cartridge product (P000021/S2) was approved by the FDA, the insert sheet stated to use the TPSA Calibrator, RC 459, in the US and T/F PSA Calibrator, RC 452, outside the US. Both RC 459 and RC 452 have the same formulation but different packaging and labeling. We created two separate calibrator products at the FDA's request since we did not have approval for the Free PSA FLex® at the time we initiated sale of the Total PSA Flex®. We now have approval for the Free PSA product and intend to revise the Total PSA Flex® insert sheet to remove reference to the TPSA Calibrator, RC459. This latter product will no longer be available for sale.

Conclusion: The revised PSA Flex® reagent cartridge is substantially equivalent in principle and performance to the current PSA Flex® reagent cartridge.

George M. Plummer
Regulatory Affairs and Compliance Manager
Date: April 25, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 15 2003

Mr. George M. Plummer
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714

Re: k031343
Trade/Device Name: TPSA Flex® reagent cartridge
Regulation Number: 21 CFR 866.6010
Regulation Name: Carcinoembryonic antigen (CEA) immunological test system
Regulatory Class: Class II
Product Code: LTJ; JIT
Dated: April 25, 2003
Received: April 29, 2003

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

K031343

Device Name: TPSA Flex® reagent cartridge

Indications for Use:
The TPSA method for the Dimension® RxL clinical chemistry system with the heterogeneous immunoassay module is an *in vitro* diagnostic test intended to quantitatively measure prostate specific antigen (PSA) in human serum and plasma:

1. as an aid in the detection of prostate cancer when used in conjunction with digital rectal exam (DRE) in men 50 years or older. Prostate biopsy is required for diagnosis of cancer
2. as an aid in the management (monitoring) of prostate cancer patients.

George M. Plummer
Regulatory Affairs and
Compliance Manager

May14, 2003

(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)

JReeves for J. Bautista
(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K031343