DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 19 2001

Edward M. Levine, Ph.D.
Director, Clinical Affairs
Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, California 90045

Re: P930027/S4
Device Name: Immulite® PSA, Immulite® Third Generation PSA, Immulite® 2000 PSA, Immulite® 2000 Third Generation PSA
Filed: January 2, 2001

Dear Dr. Levine:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) supplement for the Immulite® PSA, Immulite® Third Generation PSA, Immulite® 2000 PSA, and Immulite® 2000 Third Generation PSA.

Immulite® PSA is indicated for in vitro diagnostic use with the Immulite® Analyzer for the quantitative measurement of prostate-specific antigen (PSA) in human serum, as an aid in the detection of prostate cancer when used in conjunction with digital rectal examination (DRE) in men aged 50 years or older.

Immulite® Third Generation PSA is indicated for in vitro diagnostic use with the Immulite® Analyzer for the quantitative measurement of prostate-specific antigen (PSA) in human serum, as an aid in the detection of prostate cancer when used in conjunction with digital rectal examination (DRE) in men aged 50 years or older.

Immulite® 2000 PSA is indicated for in vitro diagnostic use with the Immulite® 2000 Analyzer for the quantitative measurement of prostate-specific antigen (PSA) in human serum, as an aid in the detection of prostate cancer when used in conjunction with digital rectal examination (DRE) in men aged 50 years or older.

Immulite® 2000 Third Generation PSA is indicated for in vitro diagnostic use with the Immulite® 2000 Analyzer for the quantitative measurement of prostate-specific antigen (PSA) in human serum, as an aid in the detection of prostate cancer when used in conjunction with digital rectal examination (DRE) in men aged 50 years or older.

These assays were previously approved or cleared for marketing as an adjunctive test to aid in the management of prostate cancer patients (P930027/S1, K972095, K972021, and K974842).

The PMA supplement is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of these devices as modified upon receipt of this letter.

The sale, distribution and use of these devices are restricted to prescription use in accordance with 21 CFR 801.109. Expiration dating for these devices have been established and approved at one year when stored at 2-8°C.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling affected by this supplement in final printed form. As part of our reengineering effort, the Office of Device Evaluation is piloting a new process for review of final printed labeling. The labeling will not routinely be reviewed by FDA staff when PMA supplement applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment. Please see the CDRH Pilot for Review of Final Printed Labeling document at http://www.fda.gov/cdrh/pmat/pilotpmat.html for further details.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Joseph Hackett, Ph.D., at (301) 594-1293.

Sincerely yours,

for 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