K973244

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AUG 3 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 9700 PSA IRMA Kit
Classification Name: Immunoradiometric Assay for PSA
Analyte Code and Name: PSA
Regulatory Class: II

Submitter: John Class
Diagnostic Systems Laboratories, Inc.
445 Medical Center Boulevard
Webster, Texas 77598
Phone:281-332-9678

Date: July 28, 1998

The DSL 9700 PSA IRMA kit was developed for the quantitative measurement of Total PSA in human serum. The IRMA format is a non-competitive assay in which the analyte to be measured is "sandwiched" between two antibodies. The first antibody is immobilized to the coated tube, the other antibody is radiolabelled for detection. The analyte present is bound by both the antibodies to form a "sandwich" complex. Unbound materials are removed by decanting and washing the tube. The resultant is analyzed in a gamma counter for net counts. The amount of bound PSA is directly proportional to the concentration of the PSA present in the sample.

The DSL PSA IRMA assay is intended for the quantitative determination of PSA in human serum to aid in the management (monitoring the reoccurrence of prostate cancer) of prostate cancer patients.

The DSL 9700 PSA IRMA is substantially equivalent to the DPC IMMULITE PSA assay.

To demonstrate substantial equivalence between the two assays, human serum samples (n = 286) were collected and assayed using both methods. Samples were chosen based on expected PSA levels so that samples with low, intermediate and high levels would be evaluated. Linear regression analysis of the results obtained for the comparison gave the equation Y = 1.25(DPC IMMULITE) + 0.33 with a correlation coefficient of (r) = 0.97.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 3 1998

Mr. John Class
Diagnostic Systems Laboratories, Inc.
445 Medical Center Boulevard
Webster, Texas 77598

Re: K973244/S2
Trade Name: Active™ PSA IRMA (DSL-9700)
Regulatory Class: II
Product Code: LTJ
Dated: June 9, 1998
Received: June 9, 1998

Dear Mr. Class:

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 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). 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 requirements, 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.

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 (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
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973244

Device Name: Active™ PSA IRMA

Indications For Use:

The DSL-9700 Active™ PSA Immunoradiometric Assay (IRMA) Kit provides materials for the quantitative measurement of Total PSA in human serum to aid in the management (monitoring the reoccurrence of prostate cancer) of prostate cancer patients. This assay is intended for *in vitro* diagnostic use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K973244

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