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445 Medical Center Boulevard
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JUN 16 1997

K971823

SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 10-4000 ACTIVE™ Testosterone EIA Kit
Classification Name: Enzymeimmunoassay, Testosterone
Analyte Code and Name: Testosterone
Regulatory Class: I

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

Date: May 14, 1997

The DSL ACTIVE™ Testosterone EIA kit was developed for the quantitative measurement of Testosterone in human serum. The EIA format is a competitive binding protein assay. Enzyme-labeled Testosterone competes with un-labeled Testosterone in the serum sample for binding sites with the Anti-Testosterone antibody in microtitration wells. Separation of free from bound Testosterone is achieved by washing and decanting the microtiter plates after incubation. The resultant is analyzed in a spectrophotometer for absorbance. The amount of enzyme-labeled Testosterone bound to the antibody is inversely proportional to the concentration of the Testosterone present in the sample.

The DSL ACTIVE™ Testosterone EIA assay is intended for the quantitative determination of Testosterone in human serum. The measurement of Testosterone is used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and in females hirsutism and virilization due to tumors, polycyctic ovaries and adrenogenital syndromes.

The DSL ACTIVE™ Testosterone EIA is substantially equivalent to the DSL Testosterone RIA.

To demonstrate substantial equivalence between the two assays, human serum samples (n = 150) were collected and assayed using both methods. Samples were chosen based on expected Testosterone 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 $Y = 0.0.94(X) + 0.1$ with a correlation coefficient of (r) = 0.93.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 16 1997

John Willis
Director of Regulatory Affairs
Diagnostic Systems Laboratories, Inc.
445 Medical Center Boulevard
Webster, Texas 77598

Re: K971823
Active Testosterone EIA
Regulatory Class: I
Product Code: CDZ
Dated: May 14, 1997
Received: May 16, 1997

Dear Mr. Willis:

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 (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

510(k) Number (if known):

Device Name: ACTIVE™ Testosterone EIA

Indications For Use:

The DSL-10-4000 ACTIVE™ Testosterone Enzymeimmunoassay (EIA) Kit provides materials for the quantitative measurement of testosterone in serum. This assay is intended for *in vitro* diagnostic use. Measurement of testosterone is used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and in females hirsutism and virilization due to tumors, polycystic ovaries and adrenogenital syndrome.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K971823

(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)