



MAY 27 1998

K981607

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445 Medical Center Boulevard
Webster Texas 77598-4217 USA
Tel 281.332.9678
Fax 281.554.4220

Customer Assistance Center
Tel 800.231.7970
Fax 281.338.1895
Email mktg@dslabs.com

SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 25100 ACTIVE™ Renin Coated Tube IRMA Kit
Classification Name: Immunoradiometric Assay, Renin
Analyte Name: Renin
Regulatory Class: II

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

Date: May 4, 1998

The DSL ACTIVE™ Renin Coated Tube IRMA kit was developed for the quantitative measurement of active renin in human serum or plasma. This Coated Tube IRMA format is a capture assay. Anti-human renin mouse monoclonal antibody to renin is immobilized to the surface of the coated bead. Renin in the standards or samples is "sandwiched" between this monoclonal antibody and the anti-human Renin mouse monoclonal antibody radiolabeled for detection with I-125.

The DSL ACTIVE™ Renin Coated Tube IRMA assay is intended for the quantitative determination of active renin in human serum or plasma. This assay is intended for *in vitro* diagnostic use. Renin measurements are used in the diagnosis and treatment of certain types of hypertension.

The DSL ACTIVE™ Renin Coated Tube IRMA is substantially equivalent to the Nichols Diagnostics ACTIVE Renin IRMA. Both kits have the same intended use.

To demonstrate substantial equivalence between the two assays, patient samples (n=53) were collected and assayed simultaneously by both methods. Samples were chosen based on expected Renin levels so those samples with low, intermediate and high levels of Renin would be evaluated. Linear regression analysis of the results obtained for the comparison with the Renin assay gave the equation $Y = 0.94(X) - 5.3$ with a correlation coefficient of $(r) = 0.94$.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 27 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K981607
ACTIVE™ Renin IRMA
Regulatory Class: II
Product Code: CIB
Dated: April 30, 1998
Received: May 5, 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 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.

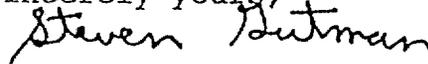
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



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Email mktg@dslabs.com

510(k) Number (if known):

Device Name: ACTIVE™ Renin Coated Tube IRMA Kit

Indications For Use:

The DSL ACTIVE™ Renin Coated Tube IRMA assay is intended for the quantitative determination of Renin in human serum or plasma. This assay is intended for *in vitro* diagnostic use. Renin measurements are used in the diagnosis and treatment of certain types of hypertension.

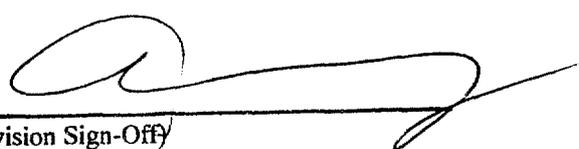
(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use


(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K981607