



K973514

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OCT 31 1997

Customer Assistance Center
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SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 9300 ACTIVE™ I-PTH Coated Bead IRMA Kit
Classification Name: Immunoradiometric Assay, I-PTH
Analyte Name: Intact Parathyroid Hormone
Regulatory Class: II

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

Date: September 16, 1997

The DSL ACTIVE™ I-PTH Coated Bead IRMA kit was developed for the quantitative measurement of the intact molecule PTH in human serum. This Coated Bead IRMA format is a capture assay. Goat polyclonal antibody to PTH is immobilized to the surface of the coated bead. I-PTH in the standards or serum samples is "sandwiched" between this polyclonal antibody and the anti-I-PTH goat polyclonal antibody radiolabeled for detection with I-125.

The DSL ACTIVE™ I-PTH Coated Bead IRMA assay is intended for the quantitative determination of I-PTH in human serum. This assay is intended for *in vitro* diagnostic use. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia (abnormally high levels of calcium in the blood) and hypocalcemia (abnormally low levels of calcium in the blood) resulting from disorders of calcium metabolism.

The DSL ACTIVE™ I-PTH Coated Bead IRMA is substantially equivalent to the DSL 8000 ACTIVE™ I-PTH IRMA. Both kits have the same intended use.

To demonstrate substantial equivalence between the two assays, patient samples (n = 97) were collected and assayed simultaneously by both methods. Samples were chosen based on expected I-PTH levels so that samples with low, intermediate and high levels of I-PTH would be evaluated. Linear regression analysis of the results obtained for the comparison with the I-PTH assay gave the equation $Y = 0.93(X) + 33.81$ with a correlation coefficient of $(r) = 0.97$.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 31 1997

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

Re: K973514
DSL 9300 ACTIVE I-PTH Coated Bead IRMA Kit
Regulatory Class: II
Product Code: CEW
Dated: September 16, 1997
Received: September 17, 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.

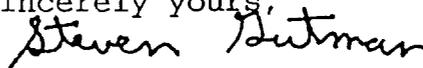
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the 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.

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

510(k) Number (if known):

Device Name: ACTIVE™ Intact PTH IRMA

Indications For Use:

The DSL ACTIVE™ I-PTH Coated Bead IRMA assay is intended for the quantitative determination of I-PTH in human serum. This assay is intended for *in vitro* diagnostic use. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia (abnormally high levels of calcium in the blood) and hypocalcemia (abnormally low levels of calcium in the blood) resulting from disorders of calcium metabolism.

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 Diagnosis and Control
510(k) Number 297354