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K981871

NOV 9 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 10-42100 C-Reactive Protein ELISA
Classification Name: Enzyme-Linked Immunosorbent Assay
Analyze Code and Name: C-Reactive Protein
Regulatory Class: II

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

Date: May 28, 1998

The DSL C-Reactive Protein (CRP) ELISA kit was developed for the quantitative measurement of CRP in human serum. The ELISA format is a capture assay. Rabbit anti-human polyclonal antibody against CRP is immobilized to the inner surface of the microtiter plate wells. CRP in the standards or serum samples is "sandwiched" between this antibody and the anti-CRP rabbit polyclonal antibody conjugated to horseradish peroxidase enzyme.

The DSL CRP ELISA assay is intended for the quantitative determination of CRP in human serum. The measurement of CRP aids in the evaluation of the amount of injury to body tissues.

The DSL CRP ELISA is substantially equivalent to the Hemagen Diagnostics, Inc. 34-40 Bear Hill Road, Waltham, MA 02154, CRP 150 Kit 510(k) No. K944288. These kits have the same intended use.

To demonstrate substantial equivalence between the two assays, patient samples (n=79) were collected and assayed simultaneously by both methods. Samples were chosen from male and female subjects with low, medium and high serum CRP levels. Linear regression analysis of the results obtained for the comparison with the CRP assay gave the equation $Y=0.827x + 349.44$ with a correlation coefficient of $(r) = 0.98$.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 9 1998

John Class
DIAGNOSTIC SYSTEMS LABORATORIES, INC.
445 Medical Center Boulevard
Webster, TX 77598

Re: K981871
Trade Name: DSL 10-42100 C-Reactive Protein ELISA
Regulatory Class: II
Product Code: DCK
Dated: August 20, 1998
Received: August 21, 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

501(k) Number (if known): K981871

Device Name: C-Reactive Protein ELISA, DSL-10-42100

Indications for use:

The DSL-10-42100 C-Reactive Protein (CRP) Enzyme-Linked Immunosorbent Assay (ELISA) Kit provides materials for the quantitative measurement of CRP in human serum. The measurement of CRP aids in the evaluation of the amount of injury to body tissues.

(PLESE DO NOT WRITE BELOW THIS LINE, CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maddux

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981871

OK - 21

Prescrition Use ✓ OR Over-The-Counter _____