JUN 1 1999

510(k) Summary

Submitter's Name/Address
Abbott Laboratories
1920 Hurd Drive
Irving, Texas 75038

Contact Person
Linda Morris
Senior Regulatory Specialist MS 1-8
Regulatory Affairs
(972) 518-6711
Fax (972) 753-3367

Date of Preparation of this Summary: April 19, 1999

Device Trade or Proprietary Name: CRP

Device Common/Usual Name or Classification Name: C-Reactive Protein

Classification Number/Class: Class II

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K991372.

Test Description:

C-Reactive Protein is an *in vitro* diagnostic assay for the quantitative determination of C-reactive protein in human serum and plasma. Antigen in the sample bonds to the specific antibody in the reagent, forming an immune complex. The immune complex causes an increase in light scattering, measured by reading turbidity at 340 nm and 700 nm, which correlates with the concentration of C-reactive protein in the sample.

Substantial Equivalence:

The C-Reactive Protein assay is substantially equivalent to the Boehringer Mannheim® C-Reactive Protein assay (K930621) on the Hitachi® 717 Analyzer.

These assays yield similar Performance Characteristics.

Similarities:

- Both assays are *in vitro* immunoturbidimetric methods.
- Both assays can be used for the quantitative determination of C-reactive protein.
- Both assays yield similar clinical results.
- Both assays are based on the light scattering properties of antigen-antibody complexes.

Differences:

- There is a difference in the assay range.

Intended Use:

The C-Reactive Protein assay is used for the quantitation of C-reactive protein in human serum and plasma.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET™ System.. The C-Reactive Protein assay method comparison yielded acceptable correlation with the Boehringer Mannheim C-Reactive Protein assay on the Hitachi 717 Analyzer. The correlation coefficient = 0.9963, slope = 1.093, and the Y-intercept = 0.203 mg/dL. Precision studies were conducted using the C-Reactive Protein assay. Within-run, between-run, and between-day studies were performed using two levels of control material. The total %CV for Level 1/Panel 401 control is 4.5% and Level 2/Panel 402 is 2.8%. The C-Reactive Protein assay range is up to 12.68 mg/dL. The limit of quantitation (sensitivity) of the C-Reactive Protein assay is 0.263 mg/dL. These data demonstrate that the performance of the C-Reactive Protein assay is substantially equivalent to the performance of the Boehringer Mannheim C-Reactive Protein assay on the Hitachi 717 Analyzer.

Conclusion:

The C-Reactive Protein assay is substantially equivalent to the Boehringer Mannheim C-Reactive Protein assay on the Hitachi 717 Analyzer as demonstrated by results obtained in the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 1 1999

Ms. Linda Morris
Senior Regulatory Specialist
Regulatory Affairs
Abbott Laboratories
1920 Hurd Drive
Irving, Texas 75038

Re: K991372
Trade Name: C-Reactive Protein (CRP)
Regulatory Class: II
Product Code: DCN
Dated: April 19, 1999
Received: April 20, 1999

Dear Ms. Morris:

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.

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/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): K991372

Device Name: C-Reactive Protein

Indications For Use:

The C-Reactive Protein assay is used for the quantitation of C-reactive protein in human serum and plasma. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991372

(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)

(Optional Format 1-2-96)