K 030899

JUL 2 2003

510(k) Summary

Submitter's Name/Address
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Contact Person
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Date of Preparation of this Summary:	March 20, 2003
Device Trade or Proprietary Name:	C-Reactive Protein
Device Common/Usual Name or Classification Name:	C-Reactive Protein
Classification Number/Class:	DCN, 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: _____.

Test Description:

C-Reactive Protein is an in vitro diagnostic assay for the quantitative determination of C-reactive protein in human serum or plasma. The C-reactive protein is a latex enhanced immunoturbidimetric assay that involves an antigen-antibody reaction between the C-reactive protein in the sample and the anti-C-reactive protein, which has been adsorbed to latex particles. The resulting agglutination is detected as an absorbance change, with the magnitude of the change being proportional to the quantity of C-reactive protein in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.

Substantial Equivalence:

The C-Reactive Protein assay is substantially equivalent to the Dade Behring N High Sensitivity CRP (K991385) on the Dade Behring BN™ 100.

Both assays yield similar Performance Characteristics.

Similarities:

- Both assays are in vitro immunoassays.
- Both assays can be used for the quantitative determination of C-reactive protein in human serum or plasma.
- Both assays yield similar clinical results.
- Both assays require calibration with calibrators.
- Both assays are based on the measurement of the agglutination following antigen-antibody reaction.

Differences:

- There is a difference between the assay ranges.
- The C-Reactive Protein assay measures the intensity of transmitted light. The Dade Behring N High Sensitivity assay measures the intensity of scattered light.

Intended Use:

The C-Reactive Protein assay is used for the quantitative analysis 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 Dade Behring N High Sensitivity CRP on the Dade Behring BN 100. On the AEROSET System, the correlation coefficient = 0.996, slope = 0.97, and the Y-intercept = 0.07 mg/dL. Precision studies were conducted using the C-Reactive Protein assay. Within-run, between-run, and between-day studies were performed using three levels of control material. On the AEROSET System, the total %CV for Level 1 ranged from 1.2 to 2.0%, Level 2 ranged from 1.0 to 2.3%, and Level 3 ranged from 1.0 to 1.3%. The C-Reactive Protein assay range is 0.22 to 30.00 mg/dL. The limit of quantitation (sensitivity) of the C-Reactive Protein assay is 0.216 mg/dL on the AEROSET System. These data demonstrate that the performance of the C-Reactive Protein assay is substantially equivalent to the performance of the Dade Behring N High Sensitivity CRP on the Dade Behring BN 100.

Conclusion:

The C-Reactive Protein assay is substantially equivalent to the Dade Behring N High Sensitivity CRP on the Dade Behring BN 100 as demonstrated by results obtained in the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 2 2003

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

Re: k030899
Trade/Device Name: C-Reactive Protein
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCN
Dated: June 12, 2003
Received: June 16, 2003

Dear Ms. Morris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030899

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 or plasma. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.

(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)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K030899