K984132

JAN 28 1999

510 (k) Summary
Safety and Effectiveness

This summary of safety and effectiveness information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Name: **Address:**	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045-5597
Telephone Number: **Facsimile Number:**	(310) 645-8200 (310) 645-9999
Contact Person:	Edward M. Levine, Ph.D. Director of Clinical Affairs
Date of Preparation:	November 16, 1998
Device Name: Trade:	IMMULITE® C-Reactive Protein
Catalog Number:	LKCR1 (100 tests), LKCR5 (500 tests)
CFR:	A C-reactive protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the C-reactive protein in serum and other body fluids. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.
Common:	Reagent system for the determination of C-reactive protein (CRP) in serum or plasma.
Classification:	Class II device, 82-DCK (21 CFR 866.5270)
Panel:	Immunology
Manufacturer:	Diagnostic Products Corporation (DPC) 5700 West 96th Street Los Angeles, CA 90045-5597
Establishment Registration #:	DPC's establishment Registration No. is 2017183
Substantially Equivalent Predicate Device:	VIRGO C-Reactive Protein Kit (K944288) Manufactured by Hemagen Diagnostics

Description of Device: IMMULITE® C-Reactive Protein is a two-site chemiluminescent enzyme immunometric assay for use with the IMMULITE® Automated Analyzer.

Intended Use of the Device: IMMULITE® C-Reactive Protein is a two-site chemiluminescent enzyme immunometric assay for use with the IMMULITE® Automated Analyzer and designed for the quantitative measurement of C-reactive protein (CRP) in serum or plasma. It is intended strictly for *in vitro* use as an aid in the evaluation of the amount of injury to body tissues.

Summary and Explanation of the test:

C-reactive protein (CRP) is an acute phase alpha globulin with a molecular mass of approximately 118,000 Daltons. CRP is highly conserved, composed of five identical cyclic globular subunits, and is classified as a member of pentaxins superfamily of proteins. While the precise *in vivo* functions of CRP during the inflammation state are not known, there is considerable evidence indicating a role in recognition and elimination of foreign pathogens by assisting humoral and cellular immunity. In normal individuals, hepatic cells produce CRP at constitutive levels of less than 1 mg/dL. Within 24 to 48 hours following acute tissue damage, production dramatically rises to approximately 1000 times the constitutive level. The increase in concentration in humans may last for several days before decreasing to normal levels.

Technology Comparison:

Provided for the reviewer is a comparison of DPC's IMMULITE C-Reactive Protein System vs. VIRGO C-Reactive Protein technology. This section does not contain any new information for a reviewer who is familiar with the DPC IMMULITE System based upon the review of previous IMMULITE assay submissions.

IMMULITE C-Reactive Protein is a chemiluminescent enzyme-labeled immunometric assay, based on ligand-labeled monoclonal antibody and separation by anti-ligand-coated solid phase.

The patient sample, a ligand-labeled anti-CRP monoclonal antibody and an alkaline phosphatase-labeled anti-CRP polyclonal antibody are simultaneously introduced into the Test Unit containing immobilized anti-ligand, and incubated for approximately 30 minutes at 37 °C with intermittent agitation. During this time, CRP in the sample forms an antibody sandwich complex which, in turn, binds to anti-ligand on the solid phase. Unbound conjugate is removed by a centrifugal wash; substrate is then added and the Test Unit is incubated for a further 10 minutes.

Technology Comparison (continued):

The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable intermediate. The continuous production of this intermediate results in the sustained emission of light, thus improving precision by providing a window for multiple readings. The bound complex - and thus also the photon output, as measured by the luminometer - is proportional to the concentration of CRP in the sample.

In the **VIRGO C-Reactive Protein Kit**, goat-anti-human CRP has been attached to the inner surface of microwell strips. Patient serum samples are introduced into the test wells where CRP, if present, will bind specifically to the immobilized antibody. After a washing step, the wells are filled with sheep anti-human CRP which has been conjugated to the enzyme horseradish peroxidase. The conjugate will bind any CRP trapped in the first step. In turn, the presence of the conjugate is determined by the action of peroxidase on the enzyme substrate 3,3',5,5'-tetramethylbenzidine (TMB). The plate is read at 450 nm, and CRP levels are calculated by reference to the CRP standards included with the kit.

Performance Equivalence:

Diagnostic Products Corporation asserts that the IMMULITE® C-Reactive Protein produces substantially equivalent results to other commercially marketed C-reactive protein assays, such as the VIRGO C-Reactive Protein Kit. Each product is designed for the quantitative measurement of C-reactive protein in serum. Each product is intended strictly for *in vitro* diagnostic use as an aid in the evaluation of the amount of injury to body tissues.

Method Comparison:

The IMMULITE® C-Reactive Protein procedure was compared to a commercially available immunoradiometric assay (VIRGO) on 97 patient samples, with CRP concentrations ranging from nondetectable to approximately 8.2 mg/dL. Linear regression analysis yielded the following statistics:

(IMMULITE) = 1.04 (VIRGO) + 0.01 mg/dL $r = 0.989$

Means: 0.89 mg/dL (IMMULITE)
0.87 mg/dL (VIRGO)

Conclusion:

The data presented in this summary of safety and effectiveness is the data that the Food and Drug Administration used in granting DPC substantial equivalence for IMMULITE® C-Reactive Protein.

Edward M. Levine 1/20/95

Edward M. Levine, Ph.D.
Director of Clinical Affairs

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 28 1999

Edward M. Levine, Ph.D.
Director of Clinical Affairs
Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, California 90045-5597

Re: K984132
Trade Name: IMMULITE® C-Reactive Protein
Regulatory Class: II
Product Code: DCK
Dated: November 16, 1998
Received: November 18, 1998

Dear Dr. Levine:

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.

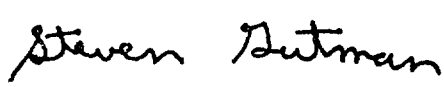
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 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): K984132

Device Name: **IMMULITE® C-Reactive Protein**

Indications For Use:

IMMULITE® C-Reactive Protein is a two-site chemiluminescent enzyme immunometric assay for use with the IMMULITE Automated Analyzer and designed for the quantitative measurement of C-reactive protein (CRP) in serum or plasma. It is intended strictly for *in vitro* use as an aid in the 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)

John E. Maykut

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984132

✓ Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use

(Optional Format 1-2-96)