K993952

DEC 16 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:	December 10, 1999
Catalog Number:	L2KCV2 (200 tests), L2KCV6 (600 tests)
Device Name **Trade:**	IMMULITE® 2000 CMV IgG
Common:	Reagent system for the detection of IgG antibodies to cytomegalovirus (CMV) in human serum.
Classification:	Class II device, LFZ (21CFR 866.3175)
Manufacturer:	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, CA 90045-5597
Establishment **Registration #:**	DPC Registration number is 2017183
Substantially Equivalent **Predicate Device:**	IMMULITE® CMV IgG (K950672)
Description of Device:	IMMULITE® 2000 CMV IgG is a clinical use device intended for use with the IMMULITE® 2000 Automated Immunoassay Analyzer

Intended Use of the Device:

IMMULITE® 2000 CMV IgG is for *in vitro* use with the IMMULITE 2000 Analyzer – for the qualitative detection of IgG antibodies to cytomegalovirus (CMV) in human serum as an aid in the determination of serological status of CMV. This kit is not FDA cleared for use in testing (i.e. screening) blood or plasma donors.

Summary and Explanation of the Test:

Cytomegalovirus (CMV), a member of the herpesvirus family, is found throughout the world. Humans of all ages are susceptible and infection is spread through sexual contact, direct exposure to infected body fluids, blood transfusions and organ transplants. The majority of infections are asymptomatic; however, CMV infections can be severe in neonates and immunocompromised individuals. Infection can also be severe in patients with congenital or acquired cellar immune defects, including cancer patients, organ recipients and AIDS patients.

CMV is the most common congenital infection, infecting between 0.5 and 2.5 percent of newborn infants. Five percent of these will develop classic cytomegalic inclusion disease with jaundice, pneumonia and central nervous system disorder. Infected infants may be asymptomatic at birth, but can develop neurological problems later in life.

Between 40 and 100 percent of people have detectable antibody, with the prevalence highest in developing countries.

Performance Equivalence - Technology Comparison:

IMMULITE® and IMMULITE® 2000 CMV IgG are chemiluminescent immunoassays. The technology in DPC's IMMULITE® 2000 CMV IgG is a unique combination of technologies employed in previously cleared and commercially marketed DPC products.

Both IMMULITE® and IMMULITE® 2000 CMV IgG assays are solid-phase, two step chemiluminescent enzyme immunoassay. The sold phase, a polystyrene bead enclosed within an IMMULITE Test Unit/IMMULITE 2000 Reaction Tube is coated with partially purified CMV antigen.

One-in-twenty one prediluted patient sample for IMMULITE/instrument-diluted patient sample for IMMULITE 2000 and a protein-based buffer are simultaneously introduced into the Test Unit (IMMULITE)/Reaction Tube (IMMULITE 2000), and incubated for approximately 30 minutes at 37°C with intermittent agitation. During this time, CMV-specific IgG in the sample binds to the CMV antigen-coated bead. Unbound serum is then removed by a centrifugal wash.

In both procedures, an alkaline phosphatase-labeled anti-human IgG antibody is introduced, and the Test Unit/Reaction Tube is incubated for another 30-minute cycle. The unbound enzyme conjugate is removed by a centrifugal wash. Substrate is then added, and the Test Unit/Reaction Tube is incubated for a further 10 minutes (IMMULITE)/5 minutes (IMMULITE 2000).

In both procedures, 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 related to the presence of CMV IgG in the sample. A qualitative result is then obtained by comparing the patient result to an established cutoff.

Performance Equivalence - Method Comparison:

The IMMULITE® 2000 CMV IgG procedure was compared to IMMULITE® CMV IgG on 229 samples, with the following result.

	IMMULITE 2000				
IMMULITE	Pos	Indeterminate	Neg		
Pos	165	0	0	Agreement:	99.6%
Indeterminate	0	0	1	Relative Sensitivity:	100%
Neg	0	0	63	Relative Specificity:	100%

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 2000® CMV IgG.

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

12/10/99
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 16 1999

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

Re: K993952
Trade Name: IMMULITE® 2000 CMV IgG
Regulatory Class: II
Product Code: LFZ
Dated: November 19, 1999
Received: November 22, 1999

Dear Dr. Levin:

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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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): K993952
Device Name: IMMULITE® 2000 CMV IgG

Indications For Use:

For *in vitro* use with the IMMULITE® 2000 Automated Analyzer - for the qualitative detection of IgG antibodies to cytomegalovirus (CMV) in human serum as an aid in the determination of serological status to CMV. This kit is not cleared for use in testing (i.e. screening) blood or plasma donors.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993952

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

(Optional Format 1-2-96)