

DEC 11 1998

**510(k) Summary
Safety and Effectiveness**

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

Name: Diagnostic Products Corporation
Address: 5700 West 96th Street
Los Angeles, California 90045

Telephone Number: (213) 776-0180

Facsimile Number: (213) 776-0204

Contact Person: Edward M. Levine, Ph.D.
Director of Clinical Affairs

Date of Preparation: June 11, 1998

Device Name:

Trade: IMMULITE Rubella Quantitative IgG

Catalog Number: LKRBQ1 (100 tests); LKRBQ5 (500 tests)

Common: Reagent system for the quantitative measure of rubella IgG antibodies in human serum.

Classification: Class III device (866.3510)

Manufacturer: Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, California 90045-5597

**Establishment
Registration #:** DPC's Registration # is 2017183

**Substantially Equivalent
Predicate Device:** Abbott Laboratories' IMx[®] Rubella IgG (K885297)

Description of Device: IMMULITE Rubella Quantitative IgG is a clinical device for use with the IMMULITE Automated Immunoassay Analyzer

Intended Use of the Device: IMMULITE Rubella Quantitative IgG is a solid-phase chemiluminescent enzyme immunoassay for use on the IMMULITE Automated Analyzer and designed for the quantitative measurement of IgG antibodies to rubella virus in human serum. It is intended strictly for *in vitro* use as an aid in the determination of immune status to rubella, particularly for women of childbearing age. The performance characteristics of this assay have not been established for use with neonate and cord blood specimens.

Summary and Explanation of the Device:

Rubella, also known as German measles, occurs throughout the world. The prodromal stage includes malaise and a low-grade fever, followed by characteristic lymphadenitis and finally a macular or maculopapular rash. While rubella is primarily an infection of children, rubella infections during the first trimester of pregnancy can result in congenital infections with disastrous consequences. Birth defects, such as deafness and/or congenital heart defects are the most common. Multiple defects such as mental retardation, cataracts and hepatosplenomegaly may also occur and contribute to death of the infant in the first year of life. Infants with congenital infections may secrete virus for up to two years. Contact with these children poses a risk to susceptible pregnant women.

Clinical symptoms of rubella infection are frequently mild or nonspecific, making the infection difficult to diagnose clinically. For these reasons, pregnant women with an undiagnosed illness with rash should be evaluated for the possibility of an acute, primary rubella infection. While the virus can be cultured *in vitro*, serology remains the principal means for establishing a clinical diagnosis of acquired rubella and congenital infections. As two-thirds of defects are not apparent at birth, it is recommended that children exposed *in utero* be monitored for clinical and serological status until school age.

A rubella vaccine, introduced in 1969, has significantly lowered the incidence of both acute disease and congenital rubella syndrome. However, as the vaccination program may vary with geographical location and as the level of immunity provided by the vaccination is not always adequate, pregnant women and women of child-bearing age are routinely screened for immune status.

The presence of rubella antibodies indicates a previous vaccination or infection and is indicative of presumptive immunity. Patients suspected of having primary, acute rubella infection should be tested for the presence of IgM antibodies.

Performance Equivalence - Technology Comparison:

Diagnostic Products Corporation (DPC) asserts that **IMMULITE® Rubella Quantitative IgG** is substantially equivalent to the **IMx® Rubella IgG** kit marketed by Abbott Laboratories (*Abbott Park, IL*).

Each product is designed for the quantitative measurement of IgG antibodies to rubella virus in human serum. Each product is intended strictly for *in vitro* diagnostic use as an aid in the determination of immune status to rubella.

IMMULITE® Rubella Quantitative IgG is a solid-phase, two-step, chemiluminescent enzyme immunoassay. The solid phase, a polystyrene bead enclosed within an IMMULITE Test Unit, is coated with a partially purified rubella antigen.

Prediluted patient sample (1-in-21 dilution) and a protein-based buffer are simultaneously introduced into the Test Unit, and incubated for approximately 30 minutes at 37°C with intermittent agitation. During this time, rubella IgG in the sample binds to the rubella antigen-coated bead. Unbound serum is then removed by a centrifugal wash.

An alkaline phosphatase-labeled anti-human IgG antibody is introduced, and the Test Unit 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 is incubated for an additional 10 minutes.

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 reading. The bound complex - and thus the photon output, as measured by the luminometer - is proportional to the presence of rubella IgG in the sample. A quantitative result is then obtained by interpolating the adjusted signal response in the master curve.

In the **IMx Rubella IgG** assay, the patient sample and diluent buffer are added to the predilution well of a reaction cell. Rubella virus coated microparticles and the diluted sample are added to an incubation well. The Rubella antibody binds to the Rubella virus coated microparticles, forming an antigen-antibody complex. Diluent buffer is added to the reaction mixture and an aliquot of the antigen-antibody complex is transferred to the glass fiber matrix. The microparticles bind irreversibly to the glass fiber matrix. The matrix is washed to remove unbound materials. The anti-human IgG/alkaline phosphatase conjugate is dispensed onto the matrix and binds to the antigen-antibody complex. Finally, the matrix is washed to remove unbound materials, the substrate, 4-Methylumbelliferyl Phosphate, is added to the matrix, and the fluorescent product is measured by the optical assembly.

Performance Equivalence - Method Comparison:

The clinical performance of the IMMULITE Rubella Quantitative IgG procedure was compared to a rubella proficiency panel obtained from the United States Centers for Disease Control and Prevention (CDC), and to the IMx assay. A summary of the results is shown in the table below. (For detailed information, see Attachments 3L and 3M)

	IMMULITE vs. CDC	IMMULITE vs. IMx	
		Study 1	Study 2
Agreement	98%	93%	88%
Sensitivity	98%	97%	90%
Specificity	100%	98%	100%
n =	100	217	200

Linear regressions analyses for 322 samples with rubella IgG antibody measurements less than 100 IU/mL yielded the following relationship between IMMULITE Rubella Quantitative IgG and Abbott Laboratories' IMx Rubella IgG in IU/mL:

$$\text{IMMULITE} = 1.02 (\text{Kit A}) - 1.55 \qquad r = 0.91$$

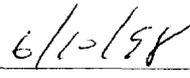
The numbers shown in the package insert may differ slightly due to rounding.

Conclusion:

The conclusions drawn from the clinical and nonclinical studies demonstrate that the device is safe, effective, and performs as well as, or better, than the current legally marketed devices.



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



Date



DEC 11 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K982078
Trade Name: IMMULITE[®] Rubella Quantitative IgG
Regulatory Class: III
Product Code: LFX
Dated: September 23, 1998
Received: September 24, 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.

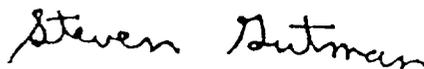
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 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): _____

Device Name: IMMULITE® Rubella Quantitative IgG

Indications For Use:

IMMULITE Rubella Quantitative is a solid-phase chemiluminescent enzyme immunoassay for use on the IMMULITE Automated Analyzer and designed for the quantitative measurement of IgG antibodies to rubella virus in human serum. It is intended strictly for *in vitro* diagnostic use as an aid in the determination of immune status to rubella, particularly for women of childbearing age. The performance characteristics of the assay have not been established for use with neonate and cord blood specimens.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Woody DeChais
(Division Sign Off)
Division of Clinical Laboratory Devices
510(k) Number K982078