2/26/99

K990222

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:	January 22, 1999
Catalog Numbers:	IMMULITE - LKCG1 (100 tests), LKCG5 (500 tests) IMMULITE 2000 - L2KCG2 (200 tests), L2KCG6 (600 tests)
Device Name **Trade:**	IMMULITE® HCG and IMMULITE® 2000 HCG
Common:	Reagent system for the measurement of HCG in human serum and urine.
Classification:	DHA, Class II device (21 CFR 862.1155)
Manufacturer:	IMMULITE HCG: Euro/DPC Limited Glyn Rhonwy Lanberis, Gwynedd LL55 4EL United Kingdom (Manufactured under a Quality System- ISO 9001/EN29001/BS 5750) IMMULITE 2000 HCG: Diagnositc Products Corporation 5700 W. 96th Street Los Angeles, CA 90045

Sole U. S. Importer:

Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, CA 90045-5597

Establishment Registration #:

Euro/DPC – Not applicable
DPC Registration number is 2017183

Substantially Equivalent Predicate Device:

IMMULITE HCG (K911796, cleared 6/20/91) and IMMULITE 2000 HCG (K911796, cleared 4/27/97)

Description of Devices:

IMMULITE HCG is a clinical use device intended for use with the IMMULITE Automated Immunoassay Analyzer.

IMMULITE 2000 HCG is a clinical use device intended for use with the IMMULITE 2000 Automated Immunoassay Analyzer.

Intended Use of the Devices:

IMMULITE HCG: For in vitro diagnostic use with the IMMULITE Automated Analyzer - for the quantitative measurement of human chorionic gonadotropin in serum, and for strictly qualitative determinations in urine, as an aid in the detection of pregnancy.

IMMULITE 2000 HCG: For in vitro diagnostic use with the IMMULITE 2000 Automated Analyzer - for the quantitative measurement of human chorionic gonadotropin in serum, and for strictly qualitative determinations in urine, as an aid in the detection of pregnancy.

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® HCG and IMMULITE 2000® HCG.

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

1/22/99
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 26 1999

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

Re: K990222
Trade Name: IMMULITE® HCG Model LKCG1, LKCG5 and IMMULITE® 2000 HCG Model L2KCG2, L2KCG6
Regulatory Class: II
Product Code: DHA
Dated: January 21, 1999
Received: January 22, 1999

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 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): K990222
Device Name: IMMULITE® HCG and IMMULITE® 2000 HCG

Indications For Use:

IMMULITE HCG: For in vitro diagnostic use with the IMMULITE analyzer - for quantitative measurement of human chorionic gonadotropin (HCG) in serum, and for strictly qualitative determinations in urine, as an aid in the detection of pregnancy.

IMMULITE 2000 HCG: For in vitro diagnostic use with the IMMULITE 2000 analyzer - for quantitative measurement of human chorionic gonadotropin (HCG) in serum, and for strictly qualitative determinations in urine, as an aid in the detection of pregnancy.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990222

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓
Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)