K033234

DEC 1 2 2003

IMMULITE® 2500 Automated Immunoassay Analyzer
510(k) Summary of 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, Clinical Affairs
Date of Preparation:	October 2, 2003
Device Name: **Trade:**	IMMULITE® 2500
Catalog Number:	IM5LITE
CFR:	A discrete photometric chemistry analyzer for clinical use is a device intended to duplicate manual analytical procedures by performing automatically various steps such as pipetting, preparing filtrates, heating, and measuring color intensity. This device is intended for use in conjunction with certain materials to measure a variety of analytes. Different models of the device incorporate various instrumentation such as microanalysis apparatus, double beam, single, or dual channel photometers, and bichromatic 2-wavelength photometers. Some models of the device may include reagent-containing components that may also serve as reaction units.
Common:	Discrete photometric chemistry analyzer for clinical use.
Classification:	Class I device, JJE (21 CFR 862.2160)
Panel:	Clinical Chemistry

Manufacturer:

Corporate Headquarters:
Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, CA 90045

Instrument Manufacturer:
DPC Instrument Systems Division
62 Flanders Bartley Road
Flanders, NJ 07836
(Formerly DPC Cirrus Inc.)

Establishment Registration Number:

DPC Headquarters Registration Number: 2017183
DPC Instrument Systems Division Registration Number: 2247117

Substantially Equivalent Predicate Device:

IMMULITE 2000 (K970227)

Description of Device:

IMMULITE 2500 Automated Immunoassay Analyzer

Intended Use of the Device:

These modifications do not change the indications for use, nor the intended use from the IMMULITE 2000 to the IMMULITE 2500. The IMMULITE 2500 analyzer is an automated immunoassay system intended to assay the same broad range of analytes in patient samples as does IMMULITE 2000. The intent of the system is to impart the same automation to the same array of immunoassays in the same hospital and commercial laboratory settings as IMMULITE 2000. The system is intended to produce safe and effective performance when used by medical laboratory personnel as is the predicate system, IMMULITE 2000.

Technology:

The IMMULITE 2500 uses ¼ inch polystyrene antibody coated beads and assay specific antibody or antigen labeled with alkaline phosphatase. The chemiluminescent detection system is a phosphate ester stabilized dioxetane. Cleavage of the phosphate ester by alkaline phosphatase results in the decomposition of the dioxetane and the emission of photons, which are quantified by a luminometer and are proportional to the quantity of analyte present.

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 the IMMULITE 2500 Automated Immunoassay Analyzer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 12 2003

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

Re: k033234
Trade/Device Name: IMMULITE® 2500 Automated Immunoassay Analyzer
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: DHA; JLW; JJE
Dated: October 3, 2003
Received: October 6, 2003

Dear Dr. Levine:

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): K033234
Device Name: IMMULITE® 2500 Automated Immunoassay Analyzer

Indications For Use:
The DPC IMMULITE 2500 analyzer is an automated immunoassay system intended to assay the same broad range of analytes in patient samples as does IMMULITE 2000. The intent of the system is to impart the same automation to the same array of immunoassays in the same hospital and commercial laboratory settings as IMMULITE 2000. Examples of the array of assays to be used with the DPC IMMULITE 2500 are two for which data in support of a claim of substantial equivalence have been submitted to FDA: hCG (product code: DHA) and TSH (JLW). The system is intended to produce safe and effective performance when used by medical laboratory personnel as is the predicate system, IMMULITE 2000.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C. Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

Prescription Use X
(Per 21 CFR 801.109)

OR 510(k) K033234 Over-The-Counter Use

(Optional Format 1-2-96)