K060929

IMMULITE 2500 Vitamin B_{12}

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 (DPC) 5210 Pacific Concourse Drive Los Angeles, California 90045-6900
Telephone Number:	(310) 645-8200
Facsimile Number:	(310) 645-9999
Contact Person:	Deborah L. Morris Director, Clinical Affairs & Regulatory Submissions
Date of Preparation:	April 4, 2006
Device Name: **Trade:**	IMMULITE® 2500 Vitamin B_{12}
Catalog Number:	L5KVB
21 CFR 862.1810:	A vitamin B_{12} test system is a device intended to measure vitamin B_{12} in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.
Common:	Vitamin B_{12} test system
Classification:	Class II device; Product Code: CDD (21 CFR 862.1810)
Panel:	Clinical Chemistry
CLIA Complexity Category:	We believe the category to be moderate based on previous classification of analogous tests.
Manufacturer:	Diagnostic Products Corporation (DPC) 5700 West 96th Street Los Angeles, California 90045-5597 Diagnostic Products Corporation (DPC) 5210 Pacific Concourse Drive Los Angeles, California 90045-6900

Establishment Registration Number:

DPC's Registration Numbers are:

Diagnostic Products Corporation (DPC)
5700 West 96th Street
Los Angeles, California 90045-5597
Registration #: 2017183

Diagnostic Products Corporation (DPC)
5210 Pacific Concourse Drive
Los Angeles, California 90045-6900
Registration #: 3005250747

Substantially Equivalent Predicate Device:

IMMULITE 2000 Vitamin B_{12} (K993251)

Description of Device:

IMMULITE 2500 Vitamin B_{12} is a solid-phase, two-site chemiluminescent enzyme immunoassay for use with the IMMULITE 2500 Automated Analyzer.

Intended Use of the Device: The IMMULITE 2500 Vitamin B_{12} is for *in vitro* diagnostic use with the IMMULITE 2500 Analyzer — for the quantitative measurement of vitamin B_{12} in serum or heparinized plasma, as an aid in clinical diagnosis and treatment of anemia.

Conclusion:

The information presented in this Special 510(k) is that which the Food and Drug Administration used in granting Diagnostic Products Corporation substantial equivalence for IMMULITE 2500 Vitamin B_{12}.

IMMULITE 2500 Folic Acid
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 (DPC) 5210 Pacific Concourse Drive Los Angeles, California 90045-6900
Telephone Number:	(310) 645-8200
Facsimile Number:	(310) 645-9999
Contact Person:	Deborah L. Morris Director, Clinical Affairs & Regulatory Submissions
Date of Preparation:	April 4, 2006
Device Name: **Trade:**	IMMULITE® 2500 Folic Acid
Catalog Number:	L5KFO
21 CFR 862.1295:	A folic acid test system is a device intended to measure the vitamin folic acid in plasma and serum. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia, which is characterized by the presence of megaloblasts (an abnormal red blood cell series) in the bone marrow.
Common:	Folic Acid test system
Classification:	Class II device; Product Code: CGN (21 CFR 862.1295)
Panel:	Clinical Chemistry
CLIA Complexity Category:	We believe the category to be moderate based on previous classification of analogous tests.
Manufacturer:	Diagnostic Products Corporation (DPC) 5700 West 96th Street Los Angeles, California 90045-5597 Diagnostic Products Corporation (DPC) 5210 Pacific Concourse Drive Los Angeles, California 90045-6900

Establishment Registration Number:

DPC's Registration Numbers are:

Diagnostic Products Corporation (DPC)
5700 West 96th Street
Los Angeles, California 90045-5597
Registration #: 2017183

Diagnostic Products Corporation (DPC)
5210 Pacific Concourse Drive
Los Angeles, California 90045-6900
Registration #: 3005250747

Substantially Equivalent Predicate Device:

IMMULITE 2000 Folic Acid (K993254)

Description of Device:

IMMULITE 2500 Folic Acid is a solid-phase, two-site chemiluminescent enzyme immunoassay for use with the IMMULITE 2500 Automated Analyzer.

Intended Use of the Device: The IMMULITE 2500 Folic Acid is for *in vitro* diagnostic use with the IMMULITE 2500 Analyzer — for the quantitative measurement of folic acid in serum, heparinized plasma or ascorbic acid-treated whole blood, as an aid in clinical diagnosis and treatment of anemia.

Conclusion:

The information presented in this Special 510(k) is that which the Food and Drug Administration used in granting Diagnostic Products Corporation substantial equivalence for IMMULITE 2500 Folic Acid.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 28 2006

Ms. Deborah L. Morris
Director of Clinical Affairs & Regulatory Submissions
Diagnostic Products Corporation
5210 Pacific Concourse Drive
Los Angeles CA 90045

Re: k060929
Trade/Device Name: IMMULITE 2500 Vitamin B12
IMMULITE 2500 Folic Acid
Regulation Number: 21 CFR§862.1810
Regulation Name: Vitamin B_{12} test system
Regulatory Class: Class II
Product Code: CDD, CGN
Dated: April 4, 2006
Received: April 5, 2006

Dear Ms. Morris:

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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060929

Device Name: IMMULITE 2500 Vitamin B12

Indications For Use:

The IMMULITE 2500 Vitamin B12 assay is for *in vitro* diagnostic use with the IMMULITE 2500 Analyzer — for the quantitative measurement of vitamin B12 in serum or heparinized plasma, as an aid in clinical diagnosis and treatment of anemia.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division [illegible]

[illegible] In Vitro Diagnostic Device
[illegible] and Safety

510(k) K060929

Indications for Use

510(k) Number (if known): K060929

Device Name: IMMULITE 2500 Folic Acid

Indications For Use:

The IMMULITE 2500 Folic Acid is for *in vitro* diagnostic use with the IMMULITE 2500 Analyzer — for the quantitative measurement of folic acid in serum, heparinized plasma or ascorbic acid-treated whole blood, as an aid in clinical diagnosis and treatment of anemia.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060929