K034055

JAN 2 1 2004

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:	December 24, 2003
Device Name:	
Trade:	IMMULITE® 2500 CK-MB
Catalog Number:	L5KCP2 (200 tests), L5KCP6 (600 tests)
CFR:	A creatine phosphokinase/creatine kinase or isoenzymes test system is a device intended to measure the activity of the enzyme creatine phosphokinase or its isoenzymes (a group of enzymes with similar biological activity) in plasma and serum. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.
Common:	Reagent system for the determination of creatine kinase isoenzyme MB (CK-MB) in serum or heparinized plasma.
Classification:	Class II device, JHX (21CFR 862.1215)
Panel:	Clinical Chemistry
CLIA Complexity Category:	We believe the category to be moderate, based on previous classification of analogous tests.
Manufacturer:	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045-5597
Establishment Registration Number:	DPC's Registration Number is 2017183

Substantially Equivalent Predicate Device: IMMULITE/IMMULITE 1000 *Turbo* CK-MB (K022118)

Description of Device: IMMULITE 2500 CK-MB is a solid-phase, two-site chemiluminescent enzyme immunoassay for use with the IMMULITE 2500 Automated Analyzer.

Intended Use of the Device:

IMMULITE 2500 CK-MB is a solid-phase, two-site chemiluminescent enzyme immunoassay for use with the IMMULITE 2500 Automated Analyzer and is intended strictly for *in vitro* diagnostic use for the quantitative measurement of creatine kinase isoenzyme MB (CK-MB) in heparinized plasma or serum, as an aid in patient management and the assessment of prognosis of myocardial infarction.

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 2500 CK-MB.

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:	December 24, 2003
Device Name:	
Trade:	IMMULITE® 2500 Myoglobin
Catalog Number:	L5KMY2 (200 tests), L5KMY6 (600 tests)
CFR:	A myoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the myoglobin (an oxygen storage protein found in muscle) in serum and other body fluids. Measurement of myoglobin aids in the rapid diagnosis of heart or renal disease.
Common:	Reagent system for the determination of myoglobin in serum and plasma.
Classification:	Class II device, DDR (21CFR 866.5680)
Panel:	Clinical Chemistry
CLIA Complexity Category:	We believe the category to be moderate, based on previous classification of analogous tests.
Manufacturer:	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045-5597
Establishment Registration Number:	DPC's Registration Number is 2017183
Substantially Equivalent	

Predicate Device: IMMULITE/IMMULITE 1000 *Turbo* Myoglobin (K991796)

Description of Device: IMMULITE 2500 Myoglobin is a solid-phase, two-site chemiluminescent enzyme immunoassay for use with the IMMULITE 2500 Automated Analyzer.

Intended Use of the Device:

IMMULITE 2500 Myoglobin is a solid-phase, two-site chemiluminescent enzyme immunoassay for use with the IMMULITE 2500 Automated Analyzer and is intended strictly for *in vitro* diagnostic use for the quantitative measurement of myoglobin in serum and heparinized plasma, as an aid in the diagnosis of acute myocardial infarction (AMI).

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 2500 Myoglobin.

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:	December 24, 2003
Device Name:	
Trade:	IMMULITE® 2500 STAT Troponin I
Catalog Number:	L5KSTI2 (200 tests), L5KSTI6 (600 tests)
CFR:	Device intended to measure the activity of the enzyme creatine kinase isoenzymes (a group of enzymes with similar biological activity) in plasma and serum. Measurements of creatine phosphokinase isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.
Common:	Reagent system for the determination of troponin I in serum and plasma.
Classification:	Class II device, MMI (21CFR 866.1215)
Panel:	Clinical Chemistry
CLIA Complexity Category:	We believe the category to be moderate, based on previous classification of analogous tests.
Manufacturer:	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045-5597
Establishment Registration Number:	DPC's Registration Number is 2017183
Substantially	

Equivalent Predicate Device: IMMULITE/IMMULITE 1000 *Turbo* Troponin I (K991795)

Description of Device: IMMULITE 2500 STAT Troponin I is a solid-phase, two-site chemiluminescent enzyme immunoassay for use with the IMMULITE 2500 Automated Analyzer.

Intended Use of the Device:

IMMULITE 2500 STAT Troponin I is a solid-phase, two-site chemiluminescent enzyme immunoassay for use with the IMMULITE 2500 Automated Analyzer and is intended strictly for *in vitro* diagnostic use for the quantitative measurement of troponin I in serum, heparinized or EDTA plasma, as an aid in the diagnosis of acute myocardial infarction (AMI).

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 2500 STAT Troponin I.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 1 2004

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

Re: k034055
Trade/Device Name: Immulite® 2500 CK-MB
Immulite® 2500 Myoglobin
Immulite® 2500 STAT Troponin I
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: JHX; MMI; DDR
Dated: December 24, 2003
Received: December 30, 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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

K034055

510(k) Number (if known): _____

Device Name: IMMULITE® 2500 CK-MB
IMMULITE® 2500 Myoglobin
IMMULITE® 2500 STAT Troponin I

Indications For Use:

The IMMULITE 2500 CK-MB is for *in vitro* diagnostic use with the IMMULITE 2500 Analyzer — for the quantitative measurement of creatine kinase isoenzyme MB (CK-MB) in heparinized plasma or serum, as an aid in patient management and the assessment of prognosis of myocardial infarction.

The IMMULITE 2500 Myoglobin is for *in vitro* diagnostic use with the IMMULITE 2500 Analyzer — for the quantitative measurement of myoglobin in serum and heparinized plasma, as an aid in the diagnosis of acute myocardial infarction (AMI).

The IMMULITE 2500 STAT Troponin I is for *in vitro* diagnostic use with the IMMULITE 2500 Analyzer — for the quantitative measurement of troponin I in serum, heparinized or EDTA plasma, as an aid in the diagnosis of acute myocardial infarction (AMI).

(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 (Per 21 CFR 801.109) 510(k) K034055 Over-The-Counter Use

(Optional Format 1-2-96)