JUL 2 2 2002

K022118

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:	June 28, 2002
Device Name:	
Trade:	IMMULITE® *Turbo* CK-MB
Catalog Number:	LSKCP1 (100 tests), LSKCP5 (500 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 CK-MB (K004002)

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

Intended Use of the Device:

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

Technology:

IMMULITE *Turbo* CK-MB is a solid-phase, two-site chemiluminescent immunometric assay, based on ligand-labeled monoclonal antibody and separation by anti-ligand-coated solid phase.

The patient sample, a ligand-labeled anti-CK-MB monoclonal antibody and an alkaline phosphatase-labeled anti-CK-BB monoclonal antibody are simultaneously introduced into the Test Unit containing immobilized anti-ligand, and incubated for approximately 6 minutes at 37°C with intermittent agitation. During this time, CK-MB in the sample forms an antibody sandwich complex which, in turn, binds to anti-ligand on the solid phase. Unbound conjugate is removed by a centrifugal wash; substrate is then added and the Test Unit is incubated for a further 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 readings. The bound complex - and thus also the photon output, as measured by the luminometer - is proportional to the concentration of CK-MB in the sample.

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 *Turbo* CK-MB.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 2 2 2002

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

Re: k022118
Trade/Device Name: IMMULITE® Turbo CK-MB
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: JHX
Dated: June 28, 2002
Received: July 1, 2002

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022118
Device Name: IMMULITE® *Turbo* CK-MB

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022118