4/27/99

K991277

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:	April 13, 1999
Device Name:	
Trade:	IMMULITE® Myoglobin
Catalog Number:	LKMY1 (100 tests), LKMY5 (500 tests)
Common:	Reagent system for the determination of myoglobin in serum and heparinized plasma.
Classification:	Class II device, 75-DDR (21CFR 866.5680)
Manufacturer:	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045-5597
Sole U.S. Importer:	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:	ACS:180 Myoglobin (K974325) Manufactured by Chiron Diagnostics
Description of Device:	IMMULITE® Myoglobin is a clinical device for use with the IMMULITE® Automated Immunoassay Analyzer.

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Intended Use of the Device:

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

Performance Equivalence:

Diagnostic Products Corporation (DPC) asserts that the IMMULITE® Myoglobin produces substantially equivalent results to other commercially marketed myoglobin assays, such as the ACS:180 Myoglobin. Each product is intended strictly for *in vitro* diagnostic use to aid in the clinical diagnosis of acute myocardial infarction.

Summary and Explanation of the Test:

Acute myocardial infarction (AMI) disrupts cardiac cell membranes, releasing intracellular cardiac proteins into the vascular system. Some of the proteins, including myoglobin, creatine kinase-MB (CK-MB), lactate dehydrogenase type 1 (LD1), and cardiac troponin subunits I and T, have proven useful in diagnosing AMI. The optimal clinical utility of each marker depends on specific protein characteristics. Myoglobin, the smallest of the markers, diffuses rapidly throughout the vascular system and provides the earliest indication of AMI. Myoglobin levels become elevated 0.5-2 hours after chest pain onset and peak within 5-12 hours. The kidneys rapidly eliminate the 17.8 kDa protein from the system, restoring normal circulating concentrations within 16-36 hours. Since the protein rapidly clears from the system, myoglobin concentrations can reliably indicate reinfarction. Additionally, myoglobin measurements can preclude AMI: two consecutive low measurements, the first upon patient admission and the second 1-2 hours later, negatively predict AMI in nearly all cases. Myoglobin measurements provide early detection of reperfusion after thrombolytic treatment as well. Some unrelated patients conditions produce high myoglobin levels, decreasing test specificity. Myoglobin participates in aerobic metabolism in both skeletal and cardiac muscle cells, and high levels accompany various muscle traumas. Renal failure and other kidney problems produce high myoglobin levels as well. Most of the complications have distinct clinical symptoms that allow reliable differential diagnosis.

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Technology Comparison:

Provided for the reviewer is a comparison of DPC's IMMULITE® Myoglobin technology vs. the ACS: 180 Myoglobin technology. This section does not contain any new information for a reviewer who is familiar with the DPC IMMULITE® System based upon the review of previous IMMULITE® assay submissions.

IMMULITE® Myoglobin is a solid-phase, two-site chemiluminescent immunometric assay. The solid phase, a polystyrene bead enclosed within an IMMULITE Test Unit, is coated with a monoclonal antibody specific for myoglobin. While the patient sample and alkaline phosphatase-conjugated polyclonal antibody are incubated for approximately 30 minutes at 37 °C in the Test Unit with intermittent agitation, myoglobin in the sample is bound to form an antibody sandwich complex. Unbound conjugate is then removed by a centrifugal wash, after which substrate is 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 myoglobin in the sample.

The **ACS:180 Myoglobin** is a two-site sandwich immunoassay using direct chemiluminescent technology, which uses constant amounts of two antibodies. The first antibody, in the Lite Reagent, is a polyclonal goat anti-myoglobin antibody labeled with acridinium ester. The second antibody, in the Solid Phase, is a monoclonal mouse anti-myoglobin antibody covalently coupled to paramagnetic particles.

The system automatically performs the following steps:

- Dispenses 10 µL of sample into a cuvette
- Dispenses 100 µL of Lite Reagent and incubates the reagents for 2.5 minutes at 37 °C
- Dispenses 200 µL of Solid Phase and incubates the reagents for 5.0 minutes at 37 °C
- Separates, aspirates, and washed the cuvettes with reagent water
- Dispenses 300 µL each of Reagent 1 and Reagent 2 to initiate the chemiluminescent reaction
- Reports results according to the selected option, as described in the system operating instructions or in the online help system

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Technology Comparison (continued):

A direct relationship exists between the amount of myoglobin present in the patient sample and the amount of relative light units (RLUs) detected by the system.

Method Comparison:

The IMMULITE® Myoglobin procedure was compared to a commercially available solid phase immunoassay for myoglobin (ACS:180) on 172 patient samples, with myoglobin concentrations ranging from approximately 13 to 831 ng/mL. Linear regression analysis yielded the following statistics:

(IMMULITE®) = 0.87 (ACS:180) – 5.7 ng/mL r = 0.981

Means: 61 ng/mL (IMMULITE®)
76 ng/mL (ACS:180)

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® Myoglobin.

Edward M. Levine

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

4/13/99
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 1999

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

Re: K991277
Trade Name: IMMULITE® Myoglobin
Regulatory Class: II
Product Code: DDR
Dated: April 13, 1999
Received: April 14, 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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): K991277

Device Name: **IMMULITE® Myoglobin**

Indications For Use:

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

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991277

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)