

JAN 27 2000

K992632

**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:** Diagnostic Products Corporation  
**Address:** 5700 West 96<sup>th</sup> Street  
Los Angeles, CA 90045

**Telephone Number:** (310) 645-8200  
**Facsimile Number:** (310) 645-9999

**Contact Person:** Edward M. Levine, Ph.D.  
Director of Clinical Affairs

**Date of Preparation:** December 15, 1999

**Device Name:**  
Trade: IMMULITE<sup>®</sup> Amphetamine

Catalog Number: LKAM1 (100 tests), LKAM5 (500 tests)

CFR: An amphetamine test system is a device intended to measure amphetamine, a central nervous system stimulating drug, in plasma and urine. Measurements obtained by this device are used in the diagnosis and treatment of amphetamine use or overdose and in monitoring levels of amphetamine to ensure appropriate therapy.

Common: Reagent system for the determination of Amphetamine in urine.

**Classification:** Class II device, 91-DKZ (21 CFR 862.3100)

**Panel:** Toxicology

**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, CA 90045-5597

**Establishment  
Registration #:**

DPC's establishment Registration No. is 2017183

**Substantially Equivalent  
Predicate Device:**

DPC's Double Antibody Amphetamine (K871696)

**Description of Device:**

IMMULITE<sup>®</sup> Amphetamine is a solid-phase, chemiluminescent enzyme immunoassay for use with the IMMULITE<sup>®</sup> Automated Analyzer.

**Intended Use of the  
Device:**

IMMULITE<sup>®</sup> Amphetamine is a solid-phase, chemiluminescent enzyme immunoassay for use with the IMMULITE Automated Analyzer and designed for the qualitative measurement of Amphetamine in urine. It is intended strictly for *in vitro* diagnostic use in clinical laboratories, in the context of a program involving an established confirmatory test for Amphetamine. A cutoff of 500 ng/mL is used by the IMMULITE Amphetamine assay to identify positive and negative results.

**Summary and Explanation of the test:**

Amphetamine is a potent sympathomimetic amine capable of stimulating the central nervous system. There are two stereoisomers; *d*-amphetamine is three to four times more potent than *l*-amphetamine. The main results of an oral dose of amphetamine (10 to 30 mg) are increased alertness and wakefulness, with decreased sense of fatigue; an elevation of mood, concentration and self-confidence; and elation and euphoria. Amphetamine and similar drugs also suppress the appetite, and have been used in weight-loss programs.

Amphetamines may be metabolized by p-hydroxylation, *N*-demethylation, deamination and conjugation. Nevertheless, substantial amounts are excreted unchanged in the urine. This process is influenced by urinary pH. Low amounts are excreted unchanged in alkaline urine, but as much as 80% of a dose can be excreted in acid urine.

### **Technological Comparison to Predicate:**

**IMMULITE Amphetamine** is a solid-phase, chemiluminescent immunoassay. The solid-phase, a polystyrene bead enclosed within a IMMULITE Test Unit, is coated with a monoclonal antibody specific for amphetamine.

The patient sample and alkaline phosphatase-conjugated amphetamine are simultaneously introduced into the Test Unit and incubated for approximately 30 minutes at 37 °C with intermittent agitation. During this time, amphetamine in the samples competes with enzyme-labeled amphetamine for a limited number of antibody binding sites on the bead. Unbound enzyme 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 inversely proportional to the concentration of amphetamine in the sample. A qualitative result is then obtained by comparing the counts per second (cps) of the patient sample to those of a sample - the Adjustor supplied with the kit - representing the assay's 500 ng/mL cutoff.

**DPC's Double Antibody Amphetamine** procedure is a competitive radioimmunoassay in which 125I-labeled amphetamine competes with amphetamine in the sample for antibody sites. After incubation for a fixed time, separation of bound from free is achieved by the PEG-accelerated double-antibody method. Finally, the antibody-bound fraction is precipitated and counted. The counts per minute in the sample tube are then compared to the counts per minute of the Positive Amphetamine Reference cutoff.

### **Performance Equivalence:**

Diagnostic Products Corporation asserts that the IMMULITE® Amphetamine produces substantially equivalent results to other commercially marketed amphetamine assays, such as DPC's Double Antibody Amphetamine assay. Each product is designed for the qualitative measurement of amphetamine in urine. Each product is intended strictly for *in vitro* diagnostic use in the context of a program involving an established confirmatory test for amphetamine and its principal metabolites.

### **Method Comparison:**

The IMMULITE Amphetamine procedure was compared to DPC's Double Antibody Amphetamine on a total of 160 urine samples from volunteer donors, presumed not to be drug abusers, and from a reference lab. The samples ranged from 200 to approximately 1000 ng/mL. A cutoff of 500 ng/mL was used for both procedures.

**IMMULITE Amphetamine**

DAb Amphetamine	Positive	Negative
Positive	32	0
Negative	3	125

Relative sensitivity: 100%  
 Relative Specificity: 98%  
 Agreement: 98%

IMMULITE Amphetamine was also compared to GC/MS results on 50 urine samples obtained similarly as above. The samples ranged from 6 to 1816 ng/mL on GC/MS. A cutoff of 500 ng/mL was used for both procedures.

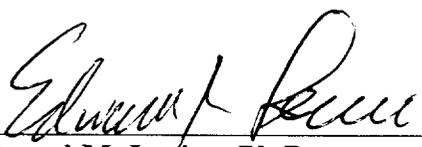
**IMMULITE Amphetamine**

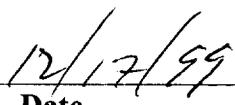
GC/MS	Positive	Negative
Positive	18	4
Negative	0	28

Sensitivity: 82%  
 Specificity: 100%  
 Agreement: 92%

**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® Amphetamine.

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

  
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**Date**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

**JAN 27 2000**

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

Re: K992632  
Trade Name: IMMULITE<sup>®</sup> Amphetamine  
Regulatory Class: II  
Product Code: DKZ  
Dated: December 17, 1999  
Received: December 20, 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.

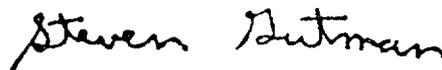
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (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.

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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 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

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

