K992634

JAN 2 0 2000

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, CA 90045
Telephone Number: **Facsimile Number:**	(310) 645-8200 (310) 645-9999
Contact Person:	Edward M. Levine, Ph.D. Director of Clinical Affairs
Date of Preparation:	November 29, 1999
Device Name: Trade:	IMMULITE® Methamphetamine
Catalog Number:	LKMA1 (100 tests), LKMA5 (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 methamphetamine 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 Coat-A-Count Methamphetamine (K885071)

Description of Device: IMMULITE® Methamphetamine is a solid-phase, chemiluminescent enzyme immunoassay for use with the IMMULITE® Automated Analyzer.

Intended Use of the Device: IMMULITE® Methamphetamine is a solid-phase, chemiluminescent enzyme immunoassay for use with the IMMULITE Automated Analyzer and designed for the qualitative measurement of methamphetamine 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 methamphetamine. A cutoff of 500 ng/mL is used by the IMMULITE Methamphetamine assay to identify positive and negative results.

Summary and Explanation of the test:

Methamphetamine is a potent sympathomimetic amine capable of stimulating the central nervous system with less peripheral actions than amphetamine. It is structurally similar to amphetamine and methylphenidate and, like them, acts through increasing the release of norepinephrine as well as through direct stimulation of postsynaptic norepinephrine receptors. There are two stereoisomers: *d*-methamphetamine is 10 times more potent as a CNS stimulant than *l*-methamphetamine, while *l*-methamphetamine (*l*-desoxyephedrine) is used in nasal inhalers for peripheral vasoconstriction. Amphetamines induce euphoria, irritability and anxiety. Tolerance and dependence have been observed.

Methamphetamine is metabolized to the active metabolite, amphetamine, hydroxylated metabolites and deaminated to hippuric and benzoic acid. It is a metabolite of benzphetamine and selegiline. About 70% of a dose is excreted in the urine in 24 hours. Methamphetamine is excreted primarily unchanged (44% to 76%) with a small fraction as 4-hydroxymethamphetamine (15%) or amphetamine (6%). The half-life of methamphetamine varies from 12 to 34 hours and is a function of urinary pH. The excretion of unchanged methamphetamine is increased in acidic urine, while in alkaline urine it is reduced to less than 5% of the dose. After a single 10 mg dose, urine concentrations ranged from 0.5 to 4.0 µg/mL in the first 24 hours. After chronic administration, methamphetamine concentrations of 25 to 300 µg/mL and amphetamine concentrations of 1 to 90 µg/mL are found in urine. However, the length of time

following drug use for which a positive result may occur is dependent upon several factors including the frequency and amount of drug, metabolic rate, excretion rate, drug half-life, and the drug user's age, weight, activity, and diet.

Technological Comparison to Predicate:

IMMULITE Methamphetamine is a solid-phase, chemiluminescent enzyme immunoassay. The solid-phase, a polystyrene bead enclosed within an IMMULITE Test Unit, is coated with a monoclonal antibody specific for methamphetamine.

The patient sample and alkaline phosphatase-conjugated methamphetamine are simultaneously introduced into the Test Unit and incubated for approximately 30 minutes at 37 °C with intermittent agitation. During this time, methamphetamine in the sample competes with enzyme-labeled methamphetamine 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 methamphetamine 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.

The **Coat-A-Count Methamphetamine** procedure is a solid-phase radioimmunoassay, wherein ^{125}I-labeled methamphetamine competes for a fixed time with methamphetamine in the patient sample for methamphetamine-specific antibody sites. Because the antibody is immobilized to the wall of a polypropylene tube, simply decanting the supernatant suffices to terminate the competition and to isolate the antibody-bound fraction of the radiolabeled methamphetamine, which is then counted in a gamma counter. The Qualitative Procedure yields positive and negative results relative to a reference chosen as a cutoff.

Performance Equivalence:

Diagnostic Products Corporation asserts that the IMMULITE® Methamphetamine produces substantially equivalent results to other commercially marketed methamphetamine assays, such as the Coat-A-Count Methamphetamine assay. Each product is designed for the qualitative measurement of methamphetamine in urine. Each product is intended strictly for *in vitro* diagnostic use in the context of a program involving an established confirmatory test for methamphetamine.

Method Comparison:

IMMULITE Methamphetamine was compared to DPC's Coat-A-Count (CAC) Methamphetamine on 214 urine samples from volunteer donors, presumed not to be drug abusers, and a reference lab. The samples ranged from undetectable to approximately 1500 ng/mL (3 times the cutoff value). A cutoff of 500 ng/mL was used for both procedures.

IMMULITE Methamphetamine

CAC Methamphetamine	Positive	Negative
Positive	45	5
Negative	0	165

Relative sensitivity:	92%
Relative Specificity:	100%
Agreement:	97%

IMMULITE Methamphetamine was also compared to GC/MS on 37 urine samples obtained similarly as above. The samples ranged from 212 ng/mL to 972 ng/mL on GC/MS. A cutoff of 500 ng/mL was used for both procedures.

IMMULITE Methamphetamine

GC/MS	Positive	Negative
Positive	14	2
Negative	3	18

Sensitivity:	88%
Specificity:	86%
Agreement:	87%

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® Methamphetamine.

Edward M. Levine 11/29/95

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

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 0 2000

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

Re: K992634
Trade Name: IMMULITE® Methamphetamine
Regulatory Class: II
Product Code: LAF
Dated: November 29, 1999
Received: November 30, 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 (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): K992634

Device Name: **IMMULITE® Methamphetamine**

Indications For Use:

IMMULITE® Methamphetamine is a solid-phase, chemiluminescent enzyme immunoassay for use with the IMMULITE Automated Analyzer and designed for the qualitative measurement of methamphetamine 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 methamphetamine. A cutoff of 500 ng/mL is used by the IMMULITE Methamphetamine assay to identify positive and negative results

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Concurrence of CDRH, Office of Device Evaluation (ODE)

✓ Prescription Use (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)