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K963916

APR 28 1997

DPC®

510 (k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Name:	Diagnostic Products Corporation (DPC)
Address:	5700 West 96th Street Los Angeles, CA 90045-5597
Telephone Number: **Facsimile Number**:	(213) 776-0180 (213) 776-0204
Contact Person:	Edward M. Levine, Ph.D. Director of Clinical Affairs
Date of Preparation:	April 3, 1997

Device Name:

Trade:	IMMULITE® Cannabinoids
Catalog #:	LKTH1 (100 tests), LKTH5 (500 tests)
Common:	Reagent system designed as a semiquantitative measurement for cannabinoids in urine.
CFR:	A device intended to measure any of the cannabinoids, hallucinogenic compounds endogenous to marijuana, in serum, plasma, saliva, and urine. Cannabinoid compounds include *delta*-9-tetrahydrocannabinol, cannabidiol, cannabinol, and cannbichromene. Measurements obtained by this device are used in the diagnosis and treatment of cannabinoid use or abuse and in monitoring levels of cannabinoids during clinical investigational use.
Classification:	Class II device (21 CFR 862.3870), 91-LDJ
Panel:	Toxicology
Accessory Trade:	IMMULITE® Cannabinoids Control Module
Common:	Quality Control Material (assayed & unassayed)
CFR:	A device intended for medical purposes for use in a test system to estimate test precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation.
Classification:	Class I device (21 CFR 862.1660), 82-JJX
Panel:	Immunology

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Manufacturer: Diagnostic Products Corporation (DPC)
5700 West 96th Street
Los Angeles, CA 90045-5597

Establishment Registration #: DPC: 2017183

Substantial Equivalent Predicate Device: Roche Abuscreen Online THC (K961620)
Abbott AxSYM Cannabinoids (K951288)
and DPC's Third Generation TSH
Control Module (K930007)

Description and Intended Use of Device:

IMMULITE® Cannabinoids is a solid-phase, chemiluminescent enzyme immunoassay designed for use with the IMMULITE® Automated Analyzer for the semiquantitative and qualitative measurement for cannabinoids and metabolites in urine. It is intended strictly for *in vitro* diagnostic use in the context of a program involving an established confirmatory test for tetrahydrocannabinol (THC, cannabis, marijuana) and its metabolites.

Substantial Equivalence Claim:

Diagnostic Products Corporation (DPC) asserts that DPC's IMMULITE® Cannabinoids is substantially equivalent to Roche Abuscreen Online THC and Abbott AxSYM Cannabinoids assays.

Intended Use Equivalence:

The IMMULITE Cannabinoids assay is designed for the semiquantitative and qualitative measurement of cannabinoids in urine. Abuscreen Online THC is an in vitro diagnostic test for the qualitative and semiquantitative detection of cannabinoids in human urine and the AxSYM Cannabinoids assay is a semiquantitative reagent system for the detection of cannabinoids in human urine. Each product is intended strictly for *in vitro* diagnostic use, and each product provides a preliminary analytical test result

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Technological Comparison to Predicate:

The IMMULITE® Cannabinoids is a chemiluminescent immunoassay. The technology of the IMMULITE® Cannabinoids assay is identical to the technology used in previously cleared and commercially marketed IMMULITE® products.

IMMULITE® Cannabinoids is a solid-phase, chemiluminescent immunoassay. The solid phase, a polystyrene bead enclosed within an IMMULITE® Test Unit, is coated with a monoclonal antibody specific for cannabinoids. The patient sample and alkaline phosphatase-conjugated 11-*nor*-Δ^9-tetrahydrocannabinol-9-carboxylic acid (THCA) are simultaneously introduced into the Test Unit, and incubated for 30 minutes at 37°C with intermittent agitation. During this time, cannabinoids in the sample compete with the enzyme-labeled THC 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 a 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 cannabinoids in the sample.

Abuscreen Online Automated Assays are based on the kinetic interaction of microparticles in a solution (KIMS) as measured by changes in light transmission. In the absence of sample drug, free antibody binds to drug-microparticle conjugates, causing the formation of particle aggregates. When a urine sample containing the drug in question is present, this drug competes with the particle-bound drug derivative for free antibody. Antibody bound to sample drug is no longer available to promote particle aggregation, and subsequent particle lattice formation is inhibited.

As the aggregation reaction proceeds in the absence of sample drug, the absorbance change increases. Conversely, the presence of sample drug diminishes the increasing absorbance in proportion to the concentration of drug in the sample. Sample drug content is determined relative to the value obtained for a known cutoff concentration of drug.

The AxSYM Cannabinoids assay utilizes fluorescence Polarization Immunoassay (FPIA) technology. In the FPIA reaction process, specimen analyte and analyte-tracer compete for binding sites on antibodies. If the specimen contains a high concentration of the analyte, then specimen analyte binds to the antibodies, leaving the analyte-tracer unbound. If the specimen contains a low concentration (or no concentration) of the analyte, then few or no analyte molecules bind to the antibodies, leaving the antibodies open for the analyte-tracer to bind. FPIA optics measure the change in polarized light to determine the concentration of unbound analyte-tracers, and therefore the concentration of analytes in the specimen (fluorescence polarization).

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Performance Equivalence - Method Comparison:

The IMMULITE Cannabinoids procedure was compared to two commercially available immunoassays for cannabinoids, Roche Abuscreen OnLine THC and Abbott AxSYM Cannabinoids Assay on a total of 456 urine samples with a range from nondetectable to over 2500 ng/mL. Randomly selected drug-free and drug-containing urine samples were obtained from a Hospital in Switzerland, and tested on site. The results of the comparisons are presented in the tables below.

		IMMULITE Cannabinoids		Relative	Relative
		Pos.	Neg.	Sensitivity	Specificity
Roche Abuscreen Online	Pos.	235	2	99.2%	98.2%
	Neg.	4	215		

The two cases where IMMULITE results were negative and Roche results were positive were both found nondetectable by the GC/MS procedure. The GC/MS values for the four cases where IMMULITE results were positive and Roche results were negative ranged from nondetectable to 80 ng/mL.

		IMMULITE Cannabinoids		Relative	Relative
		Pos.	Neg.	Sensitivity	Specificity
Abbott AxSYM	Pos.	237	9	96.3%	99.0%
	Neg.	2	208		

The nine cases where IMMULITE results were negative and Abbott AxSYM results were positive were all found nondetectable by the GC/MS procedure. The two cases where IMMULITE results were positive and Abbott AxSYM results were negative were both 18 ng/mL in the GC/MS procedure.

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Substantial Equivalence Claim for the IMMULITE Cannabinoids Control Module

Diagnostic Products Corporation (DPC) asserts that the IMMULITE Cannabinoids Control Module, which is sold separately from the IMMULITE Cannabinoids kit, is substantially equivalent to other commercially available assayed controls, such as DPC's Third Generation TSH Control Module (K930007).

Intended Use Equivalence:

Each product is designed for monitoring day-to-day performance of a particular assay. Each product is intended strictly for in vitro diagnostic use, and is supplied lyophilized, requiring reconstitution.

The controls are intended to be assayed as an unknown, in the same manner as a patient sample, in the context of an internal quality control program

Clinical Studies: Not applicable

Conclusion: The conclusions drawn from the nonclinical tests demonstrate that the device is safe, effective, and performs as well as or better than the legally marketed device.

Edward Levine — 4/4/97

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

Date