Diagnostic Products Corporation
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K963918

APR - 8 1997

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: (213) 776-0180
Facsimile Number: (213) 776-0204

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

Date of Preparation: September 27, 1996

Device Name:

Trade: IMMULITE® Cocaine Metabolite

Catalog Number: LKCN1 (100 tests), LKCN5 (500 tests)

Common: Reagent system designed for the semi-quantitative analysis of benzoylecgonine, and its parent compound, cocaine, in urine.

CFR: A device intended to measure cocaine and a cocaine metabolite (benzoylecgonine) in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of cocaine use or overdose.

Classification: Class II device (862.3250), 91-DIO

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

Establishment Registration #: 2017183

Substantially Equivalent Predicate Device: DPC's Coat-A-Count (CAC) Cocaine Metabolite (K870740)

Description and Intended Use of Device:

IMMULITE® Cocaine Metabolite is a solid-phase, chemiluminescent enzyme immunoassay designed for use with the IMMULITE® Automated Analyzer for the semi-quantitative measurement of benzoylecgonine and its parent compound, cocaine, in urine. It is intended strictly for *in vitro* diagnostic use in the context of a program involving an established confirmatory test for cocaine and its principal metabolites.

Substantial Equivalence Claim:

Diagnostic Products Corporation (DPC) asserts that DPC's IMMULITE® Cocaine Metabolite is substantially equivalent to DPC's Coat-A-Count (CAC) Cocaine Metabolite.

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Intended Use Equivalence:

Each product is designed for the semi-quantitative measurement of cocaine metabolites in urine. Each product is intended strictly for *in vitro* diagnostic use, and each product provides a preliminary analytical test result.

Performance Equivalence - Technological Comparison:

IMMULITE® Cocaine Metabolite is a chemiluminescent immunoassay. The technology in IMMULITE® Cocaine Metabolite is identical to technology used in previously cleared and commercially marketed IMMULITE® products. DPC's Coat-A-Count Cocaine Metabolite is a solid-phase ^{125} I radioimmunoassay

IMMULITE® Cocaine Metabolite is a solid-phase, chemiluminescent immunometric assay. The solid phase, a polystyrene bead enclosed within an IMMULITE® Test Unit, is coated with a monoclonal antibody specific for benzoylecgonine. The patient sample and alkaline phosphatase-conjugated benzoylecgonine are simultaneously introduced into the Test Unit, and incubated for 30 minutes at 37°C with intermittent agitation. During this time, benzoylecgonine in the sample competes with the enzyme-labeled benzoylecgonine 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, PPD (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 benzoylecgonine in the sample.

DPC's Coat-A-Count® Cocaine Metabolite is a solid-phase radioimmunoassay wherein ^{125}I-labeled benzoylecgonine competes for a fixed time with benzoylecgonine in the patient sample for sites on benzoylecgonine-specific antibody. The antibody being immobilized to the wall of a polypropylene tube, decanting the supernatant suffices to terminate the competition and to isolate the antibody-bound fraction of the radiolabeled benzoylecgonine. Counting the tube in a gamma counter than yields a number, which converts by way of a calibration curve to a measure of the benzoylecgonine present in the patient sample.

Performance Equivalence - Method Comparison:

IMMULITE® Cocaine Metabolite procedure was compared to Coat-A-Count Cocaine Metabolite on a total of 351 urine samples obtained from a drug testing laboratory, with the following results:

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Performance Equivalence - Method Comparison *(continued)*:

		Positive	Negative
CAC	Positive	229	11
	Negative	5	106

223 of the 234 specimens tested positive by the IMMULITE Cocaine Metabolite procedure were tested by the GC/MS procedure. 221 of the 223 IMMULITE positive specimens were found positive by the GC/MS procedure (cutoff 150 ng/mL), achieving a confirmation rate of 99% (221/223).

Interpretation of Results

Using a cutoff of 300 ng/mL (0.3 ug/mL), as recommended in the SAMHSA guidelines, a numerical result greater than or equal to 300 ng/mL is interpreted as *positive* for cocaine metabolite, whereas a result less than 300 ng/mL is interpreted as *negative*.

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

Date

EML/mb