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Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, CA 90045
Tel: (213) 776-0180
Fax: (213) 776-0204

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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 of Manufacturer:	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:	January 23, 1997
Device Name:	
Trade:	IMMULITE® Opiates Screen
Catalog #:	LKOS1 (100 tests), LKOS5 (500 tests)
Common:	Reagent system designed as a semi-quantitative screen for morphine-3-glucuronide in urine.
CFR:	A device intended to measure any of the addictive narcotic pain-relieving opiate drugs in blood, serum, urine, gastric contents, and saliva. An opiate is any natural or synthetic drug that has morphine-like pharmocological actions. The opiates include drugs such as morphine, morphine glucuronide, heroin, codeine, nalorphine, and meperedine. Measurements obtained by this device are used in the diagnosis and treatment of opiate use or overdose and in monitoring the levels of opiate administration to ensure appropriate therapy.
Classification:	Class II device (21 CFR 862.3650), 91-DJG
Panel:	Toxicology
Accessory Trade Name:	IMMULITE® Opiates Screen Control Module
Catalog #:	LOSCM (2 vials x 2 mL)
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

Establishment Registration #: DPC: 2017183

Substantial Equivalent Predicate Device: Emit d.a.u. Opiate Assay MultiPak (K842677), manufactured by Syva Co. Palo Alto, CA

Description and Intended Use of Device: IMMULITE® Opiates SceenOpiates Screen is a solid-phase, chemiluminescent enzyme immunoassay for use with the IMMULITE® Automated Analyzer and is designed for use as a semi-quantitative screen for opiates 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 opiates.

Substantial Equivalence Claim:

Diagnostic Products Corporation (DPC) asserts that DPC's IMMULITE® Opiates Screen is substantially equivalent to Syva's Emit d.a.u. Opiates Assay MultiPak.

Intended Use Equivalence:

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

Method Comparison:

The IMMULITE Opiates Screen procedure was compared to two commercially available immunoassays for opiates (Roche Abuscreen OnLine, manufactured by Roche Diagnostic Systems and Emit d.a.u. Opiate Assay, manufactured by Syva) and GC/MS on a total of 618 urine samples with a range from nondetectable to over 1000 ng/mL. Randomly selected drug-free and drug-containing urine samples were obtained from the Uddevalla Hospital in Uddevalla Sjukhus, Switzerland and tested on site. The results of the comparisons are presented in the tables below.

		IMMULITE Opiates Screen		Relative Sensitivity	Relative Specificity
		Pos.	Neg.		
Roche	Pos.	240	10	96.0%	98.6%
	Neg.	5	363		

Agreement: 97.6%
95% Confidence Limits for Relative Sensitivity and Specificity, respectively:
92.8% - 98.1% and 96.9% - 99.6%.

		IMMULITE Opiates Screen		Relative	Relative
		Pos.	Neg.	Sensitivity	Specificity
Syva Emit	Pos.	241	6	97.6%	98.9%
	Neg.	4	367		

Agreement: 98.4%
95% Confidence Limits for Relative Sensitivity and Specificity, respectively: 94.8% - 99.1% and 97.3% - 99.7%.

IMMULITE Opiates Screen

		Pos.	Neg.	Sensitivity	Specificity
GC/MS	Pos.	230	5	97.9%	96.1%
	Neg.	15	368		

Agreement: 96.8%
95% Confidence Limits for Sensitivity and Specificity, respectively: 95.1% - 99.3% and 93.6% - 97.8%.

In the comparison between IMMULITE and Roche Abuscreen OnLine, 8 of the 10 "false negative" cases were negative by GC/MS and 2 of the 5 "false positive" cases were positive by GC/MS. In the comparison between IMMULITE and Syva Emit, 2 of the 6 "false negative" cases were negative by GC/MS and none of the 4 "false positive" cases were positive by GC/MS.

IMMULITE Opiates Screen Control Module

DPC's Opiates Screen Control Module is an assayed, bi-level control intended strictly for in vitro use in monitoring the performance and accuracy of the IMMULITE Opiates Screen assay. The two controls are supplied in liquid form, in 2 mL aliquots, and are sold separately from the IMMULITE Opiates Screen Kit.

The control values are lot-specific, i.e., the control values are established for each control lot. The values for the Opiate controls are targeted at approximately 195 and 453 ng/mL.

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

1/28/97
Date