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BECKMAN

K963673

Summary of Safety & Effectiveness
IMMAGE™ Immunochemistry System Therapeutic Drug Monitoring Reagents
[Carbamazepine (CAR), Phenobarbital (PHE), Phenytoin (PHY), and Theophylline (THE)]

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1.0 Submitted By:

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2.0 Date Submitted:

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3.0 Device Name(s):

3.1 Proprietary Names

IMMAGE™ Immunochemistry System Carbamazepine (CAR) Reagent
IMMAGE™ Immunochemistry System Phenobarbital (PHE) Reagent
IMMAGE™ Immunochemistry System Phenytoin (PHY) Reagent
IMMAGE™ Immunochemistry System Theophylline (THE) Reagent
IMMAGE™ Immunochemistry Systems Drug Calibrator 1

3.2 Classification Names

Carbamazepine Test System (Not Classified)
Phenobarbital Test System (21 CFR §862.3660)
Phenytoin Test System (Not Classified)
Theophylline Test System (21 CFR §862.3880)
Calibrator (21 CFR §862.1150)

4.0 Predicate Device(s):

IMMAGE System Reagent	Predicate	Manufacturer	Docket Number
Carbamazepine (CAR) Reagent	TDx®** Carbamazepine Reagent	Abbott* Laboratories, Inc.	K904226
Phenobarbital (PHE) Reagent	TDx Phenobarbital II Reagent	Abbott Laboratories, Inc.	K904226
Phenytoin (PHY) Reagent	TDx Phenytoin Reagent	Abbott Laboratories, Inc.	K904226
Theophylline (THE) Reagent	TDx Theophylline II Reagent	Abbott Laboratories, Inc.	K922991

*Abbott Laboratories, Abbott Park, IL 60064
**Trademark of Abbott Laboratories

5.0 Description:

The IMMAGE Immunochemistry System (TDM) CAR, PHE, PHY, and THE Reagents in conjunction with Beckman Drug Calibrator 1, are intended for use in the quantitative determination of carbamazepine, phenobarbital, phenytoin, and theophylline concentrations respectively in human serum and plasma samples on Beckman's IMMAGE Immunochemistry System.

6.0 Intended Use:

The IMMAGE Immunochemistry System Carbamazepine (CAR) reagent, when used in conjunction with the Beckman IMMAGE™ Immunochemistry Systems and Beckman Drug Calibrator 1, is intended for the quantitative determination of carbamazepine in human serum or plasma by rate nephelometric inhibition immunoassay.

The IMMAGE Immunochemistry System Phenobarbital (PHE) reagent, when used in conjunction with the Beckman IMMAGE™ Immunochemistry Systems and Beckman Drug Calibrator 1, is intended for the quantitative determination of phenobarbital in human serum or plasma by rate nephelometric inhibition immunoassay.

The IMMAGE Immunochemistry System Phenytoin (PHY) reagent, when used in conjunction with the Beckman IMMAGE™ Immunochemistry Systems and Beckman Drug Calibrator 1, is intended for the quantitative determination of phenytoin in human serum or plasma by rate nephelometric inhibition immunoassay.

The IMMAGE Immunochemistry System Theophylline (THE) reagent when, used in conjunction with the Beckman IMMAGE™ Immunochemistry Systems and Beckman Drug Calibrator 1, is intended for the quantitative determination of theophylline in human serum or plasma by rate nephelometric inhibition immunoassay.

The IMMAGE™ Immunochemistry Systems Drug Calibrator 1, used in conjunction with IMMAGE reagents, is intended for use on Beckman's IMMAGE Immunochemistry Systems for the calibration of Carbamazepine, Phenobarbital, Phenytoin, and Theophylline test systems.

7.0 Comparison to Predicate(s):

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

Reagent	Aspect/Characteristic	Comments
SIMILARITIES		
IMMAGE System (CAR, PHE, PHY, THE) Reagents	Intended use.	Same as Abbott TDx Reagents
	Liquid stable reagents.	
	Initial analytic ranges.	
DIFFERENCES		
IMMAGE System (CAR, PHE, PHY, THE) Reagents	IMMAGE utilizes nephelometric inhibition immunoassay	Abbott TDx reagents utilize fluorescence polarization immunoassay
IMMAGE System (CAR, PHE, PHY) Reagents	Antibody source for IMMAGE CAR, PHE, and PHY reagents is mouse.	Antisera source for TDx Carbamazepine, Phenytoin, and Phenobarbital is sheep.

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, and imprecision experiments that relate results obtained from the Abbott TDx Reagents to the IMMAGE System Reagents.

Method Comparison* Study Results
IMMAGE System CAR, PHE, PHY, and THE Reagents

Analyte	Slope	Intercept	r	n	Predicate Method
Carbamazepine	0.982	0.17	0.992	111	Abbott TDx Carbamazepine
Phenobarbital	0.998	-1.18	0.996	103	Abbott TDx Phenobarbital II
Phenytoin	1.051	-0.76	0.996	107	Abbott TDx Phenytoin
Theophylline	0.992	0.12	0.995	144	Abbott TDx Theophylline II

* Deming Regression statistics used

Stability Study Results

Reagent	Product Claim
IMMAGE CAR, PHE, PHY, and THE	24 month shelf-life 14 day open container stability 14 day calibration stability

Estimated Within-Run Imprecision

Sample	Mean (µg/mL)	S.D. (µg/mL)	%C.V.	N
Carbamazepine (CAR)				
Level 1	4.76	0.214	4.5	80
Level 2	6.94	0.288	4.2	80
Level 3	14.6	0.37	2.6	80

Sample	Mean (µg/mL)	S.D. (µg/mL)	%C.V.	N
Phenobarbital (PHE) Reagent				
Level 1	9.23	0.479	5.2	80
Level 2	35.2	1.14	3.2	80
Level 3	62.0	1.50	2.4	80

Sample	Mean (µg/mL)	S.D. (µg/mL)	%C.V.	N
Phenytoin (PHY) Reagent				
Level 1	8.23	0.201	2.4	80
Level 2	17.3	0.35	2.0	80
Level 3	35.9	0.59	1.7	80

Sample	Mean (µg/mL)	S.D. (µg/mL)	%C.V.	N
Theophylline (THE) Reagent				
Level 1	8.40	0.296	3.5	80
Level 2	20.5	0.48	2.3	80
Level 3	33.7	0.71	2.1	80

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.