K961824

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Roche Diagnostic Systems
A Member of the Roche Group

Roche Diagnostic Systems, Inc.
Branchburg Township
1080 U.S. Highway 202
Somerville, New Jersey 08876-3771

Direct Dial
Fax

510(k) Summary

Roche COBAS® INTEGRA Reagent Cassettes

In accordance with the Safe Medical Devices Act of 1990, a 510(k) summary is provided as outlined in 21 CFR 807.92.

I. Identification of 510(k) Sponsor:

Roche Diagnostic Systems, Inc.
a subsidiary of Hoffmann-La Roche, Inc.
Branchburg Township
1080 U.S. Highway 202
Somerville, New Jersey 08876-3771

510(k) Submission dated May 8, 1996

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II. Device Name:

The device name, including both the trade/proprietary name and the classification name are provided in the table below.

Product Name	Classification Name	Regulatory Class	CFR Classification Number	Predicate Product Name	Date Predicate Cleared	Predicate 510(k) Number
COBAS INTEGRA Albumin (ALB-T) (Turbidimetric)	Albumin immunological test system	Class II	966.5040	Behring N Antiserum to Human Albumin	4/15/86	K860894
COBAS INTEGRA HbA1c (HBA1C)	Glycosylated hemoglobin assay	Class II	864.7470	Roche Unimate HBA1c Reagent	2/9/96	K952337/S1
COBAS INTEGRA Digoxin (DIG) modification	Digoxin test system	Class II	862.3320	COBAS INTEGRA Digoxin	9/8/95	K951595

III. Identification of the legally marketed device to which the 510(k) sponsor claims equivalence:

The following table identifies the legally marketed devices to which Roche Diagnostic Systems, Inc. claims equivalence.

Product Name	Classification Name	Regulatory Class	CFR Classification Number	Predicate Product Name	Date Predicate Cleared	Predicate 510(k) Number
COBAS INTEGRA Albumin (ALB-T) (Turbidimetric)	Albumin immunological test system	Class II	966.5040	Behring N Antiserum to Human Albumin	4/15/86	K860894
COBAS INTEGRA HbA1c (HBA1C)	Glycosylated hemoglobin assay	Class II	864.7470	Roche Unimate HBA1c Reagent	2/9/96	K952337/S1
COBAS INTEGRA Digoxin (DIG) modification	Digoxin test system	Class II	862.3320	COBAS INTEGRA Digoxin	9/8/95	K951595

IV. Description of the Device/Statement of Intended Use:

Through this submission, it is the intention of Roche to gain clearance of an additional 2 COBAS Reagent Cassettes. The 2 COBAS INTEGRA Reagent Cassettes contained in this submission are intended for use with the COBAS INTEGRA Analyzer. These are the COBAS INTEGRA Cassette for Albumin-T in urine and the COBAS INTEGRA Cassette for HbA1c. The COBAS INTEGRA Cassette for Albumin (Turbidimetric) contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA for the quantitative immunological determination of human albumin in serum and urine. The COBAS INTEGRA Cassette for Hemoglobin A1c contains an in vitro diagnostic reagent system intended for the quantitative determination of percent hemoglobin (HbA1c%) in hemolysate. The COBAS INTEGRA Analyzer and COBAS INTEGRA Reagent Cassettes together provide an integrated system for *in vitro* diagnostic testing. The COBAS INTEGRA Reagent Cassettes are comprised of chemistry, drugs of abuse, immunology, therapeutic drug monitoring, and hematology assay systems. The COBAS INTEGRA Analyzer provides quantitative measurement of these analytes via three measuring principles, i.e., absorbance, fluorescence polarization and ion-selective electrodes. The COBAS INTEGRA Reagent Cassettes are compact and preparation-free with the added convenience of long term on-board stability. Sixty-eight COBAS INTEGRA Reagent Cassettes can be stored on board, 24 hours a day at 2-8°C. Each cassette is barcoded. This barcode label provides the analyzer with specific reagent information such as the lot number, the expiration date and the number of tests.

This submission also contains a modification to the previously cleared COBAS INTEGRA Reagent Cassette for Digoxin. The COBAS INTEGRA Reagent Cassette for Digoxin has been modified to include the use of heparinized samples.

V. Summary of the technological characteristics of the new device in comparison to those of the predicate.

Tables 1, 2 and 3 attached to this summary outline the technological characteristics (methodologies) of the COBAS INTEGRA Reagents in comparison to those of legally marketed predicate products.

VI. Brief discussion of the clinical and nonclinical tests relied on for a determination of substantial equivalence:

Tables 1, 2 and 3 attached to this summary demonstrate the results of clinical and nonclincal studies performed using the COBAS INTEGRA Reagent Cassettes. The significant performance characteristics relied upon for a determination of substantial equivalence are summarized in this chart. This information concludes that the performance of this device is essentially equivalent to other legally marketed devices of a similar kind.

Table 1

	COBAS INTEGRA Cassette for Albumin (Turbidimetric) in urine	**Behring N Antiserum to Human Albumin (BNA Nephelometer)**
Methodology	Immunoturbidimetric	Immunoturbidimetric
Sample type	Urine	Serum, umbilical cord serum, CSF and urine
Calibrator	Roche Serumproteins T Standard	Behring N Protein Standard PY
Reagent (active ingredients)	1. Anti-albumin T antiserum (rabbit) in phosphate buffer	1. Antiserum to human albumin 2. Phosphate buffered saline
Performance Characteristics:		
Assay range	6-193 mg/L 6-3860 mg/L w/postdilution	Not specified in labeling
Precision (Within-run)	4.3 % at 10 mg/L 1.2 % at 223 mg/L	Not specified in labeling
Accuracy	N = 200 R = 0.997 vs. Behring Albumin	Not specified in labeling
Sensitivity (Analytical)	7 mg/L	Not specified in labeling

Table 2

	COBAS INTEGRA Cassette for HbA1c		Roche Unimate HbA1c Reagent on COBAS MIRA	
Methodology	Immunoturbidimetric test for HbA1c Colorimetric test for Total Hb		Immunoturbidimetric test for HbA1c Colorimetric test for Total Hb	
Sample type	Anticoagulated venous or capillary whole blood (heparin, EDTA, citrate or oxalate/fluoride)		Anticoagulated venous or capillary whole blood (heparin, EDTA, citrate or oxalate/fluoride)	
Application	Hemolysate		Hemolysate or whole blood	
Reported measuring units	% HbA1c		% HbA1c	
Calibrator	Roche HbA1c Calibrator		Roche HbA1c Calibrator	
Reagent (active ingredients)	R1. Potassium phosphate buffer Tensides R2. Latex coated with monoclonal (mouse) antibody specific for HbA1c Bovine serum albumin NaCL HEPPS Buffer R3. Agglutinator (synthetic polyvalent antigen) Bovine serum albumin Formate buffer		R1. Latex coated with monoclonal (mouse) antibody specific for HbA1c Bovine serum albumin NaCL HEPPS Buffer R2. Potassium phosphate buffer Tensides R3. Agglutinator (synthetic polyvalent antigen) Bovine serum albumin Formate buffer	
Performance Characteristics:				
Assay range	3-30.9 %		2-25 %	
Precision (Total)	Mean % 4.8 % 12.1 %	CV % 2.8 % 2.4 %	Mean % 5.3 % 12.9 %	CV % 4.0 % 4.9 %
Accuracy	N = 240 R = 0.994 vs. Roche Unimate Reagent		N = 208 R = 0.943 vs. BM Tina-quant HbA1c Reagent	
Sensitivity (Analytical)	0.90 umol/L for hemoglobin 0.22 umol/L for HbA1c		0.76 umol/L for hemoglobin 0.78 umol/L for HbA1c	

Table 3

	COBAS INTEGRA Cassette for Digoxin (Modified)	COBAS INTEGRA Cassette for Digoxin (Cleared)
Methodology	Kinetic interaction of microparticles in solution	Kinetic interaction of microparticles in solution
Sample type	Serum and heparinized plasma	Serum
Calibrator	COBAS-FP Digoxin Calibrators (K951595)	COBAS-FP Digoxin Calibrators (K951595)
Controls	COBAS-FP TDM Controls (K954992)	COBAS-FP TDM Controls (K954992)
Reagent (active ingredients)	0 Anti-digoxin monoclonal antibody (mouse) in buffer 1 Conjugated digoxin derivative microparticles in buffer	0 Anti-digoxin monoclonal antibody (mouse) in buffer 1 Conjugated digoxin derivative microparticles in buffer
Performance Characteristics:		
Assay range	0.17 - 5.0 ng/mL	0.17 - 5.0 ng/mL
Precision (Total)	9.7 % at 0.87 ng/mL 6.1 % at 1.64 ng/mL 3.9 % at 2.82 ng/mL	14.4 % at 0.81 ng/mL 5.3 % at 1.57 ng/mL 3.8 % at 4.1 ng/mL
Accuracy	N = 63 R = 0.967 vs. TDx (FPIA)	N = 189 R = 0.958 vs. TDx (FPIA)
Sensitivity (Analytical)	0.17 ng/mL	0.17 ng/mL