

K980996

JUN 5 1998



Diagnosics

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.

The assigned 510(k) number is: _____

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 March 16, 1997

Contact: James W. Haynes
Regulatory Affairs Associate
Phone: (908) 253-7569
Fax: (908) 253-7547

II. Device Name:

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

Table 1

Proprietary Name	Classification Name	Product Code	Regulation Number
COBAS INTEGRA Carbon Dioxide (CO2-S)	Bicarbonate / carbon dioxide test system	KHS	862.1160
COBAS INTEGRA Glucose HK Liquid (GLULF)	Glucose test system	CFR	862.1345

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.

Table 2

Product Name	Predicate Product Name	K number	Date of substantial equivalence
COBAS INTEGRA Carbon Dioxide (CO2-S)	COBAS INTEGRA Carbon Dioxide (CO2)	K954992	1/25/96
COBAS INTEGRA Glucose HK Liquid (GLULF)	COBAS INTEGRA Glucose HK Liquid (GLUCL)	K972250	8/12/97

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

The COBAS INTEGRA test applications contained in this submission are intended for use with the COBAS INTEGRA Analyzer. The COBAS INTEGRA Analyzer and COBAS INTEGRA Reagent cassettes together provide an integrated system for *in vitro* diagnostic testing. The COBAS INTEGRA Analyzer along with 107 Roche COBAS INTEGRA Reagent Cassettes were previously cleared on September 8, 1995 (K951595); January 25, 1996 (K954992); July 23, 1996 (K961824); October 31, 1996 (K963292); January 21, 1997 (K964457); and August 12, 1997 (K972250).

The COBAS INTEGRA Analyzer utilizes three measuring principles, i.e., absorbance, fluorescence polarization and ion-selective electrodes. The analyzer has a throughput of up to 600 tests per hour with STAT samples prioritized and tested immediately. Random sample access, robotics and a user interface optimize time management and streamline workflow. The COBAS INTEGRA can store up to 68 COBAS INTEGRA Reagent Cassettes on board, 24 hours a day at 2-8°C. The COBAS INTEGRA Reagent Cassettes are compact and preparation-free with the added convenience of long term on-board stability. Barcode readers are used to identify newly loaded reagent cassettes, samples for patient identification, and rack inserts and to read calibration and control data from the cassette label. COBAS INTEGRA tests include chemistry, drugs of abuse, immunology, ion selective electrodes, therapeutic drug monitoring, and hematology reagents. For additional information on the COBAS INTEGRA Analyzer and its constituent modules, please refer to the Operator's Manual in Volumes 1 through 2, pages 92-703, of the original 510(k) submission (K951595).

Through this submission, it is the intention of Roche to gain clearance for one additional COBAS Reagent Cassette and one optional application for a previously approved COBAS Reagent Cassette. These are the COBAS INTEGRA Carbon Dioxide (CO2-S) and the COBAS INTEGRA Glucose (GLULF), respectively.

COBAS INTEGRA Carbon Dioxide (CO2-S):

The cassette COBAS INTEGRA Carbon Dioxide (CO2-S) contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA for the quantitative determination of the carbon dioxide concentration in serum and plasma.

COBAS INTEGRA Glucose HK Liquid (GLULF):

The cassette COBAS INTEGRA Glucose HK Liquid contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA for the quantitative determination of the glucose concentration in serum, plasma, urine and cerebrospinal fluid (CSF). In addition, an optional glucose "fast application" for serum and plasma is available.

The intended use, clinical utility and methodology of each reagent cassette are further described in the test specific COBAS INTEGRA Method Manual sheets, contained in the test specific sections of this submission.

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

Tables 3-4 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 3-4 demonstrate the results of clinical and nonclinical 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 3 - COBAS INTEGRA Carbon Dioxide (CO2-S)

	COBAS INTEGRA Carbon Dioxide (CO2-S) (proposed)		COBAS INTEGRA Carbon Dioxide (CO2) (cleared)	
Intended Use	quantitative determination of the carbon dioxide concentration in serum and plasma		quantitative determination of the carbon dioxide concentration in serum and plasma	
Methodology	enzymatic methodology with phosphoenolpyruvate carboxylase and malate dehydrogenase		enzymatic methodology with phosphoenolpyruvate carboxylase and malate dehydrogenase	
Sample type	Serum and Plasma		Serum and Plasma	
Calibrator	Roche Ammonia / Ethanol / CO2 Calibrator (K952282)		Roche Ammonia / Ethanol / CO2 Calibrator	
Controls	Roche Ammonia / Ethanol / CO2 Control Normal and Abnormal (K942048)		Roche Ammonia / Ethanol / CO2 Control Normal and Abnormal	
Reagents	Mono reagent in vial B (granulate)		Substrates in vial A (liquid) Enzymes in vial C (liquid)	
Performance Characteristics:				
Assay range	0 - 50 mmol/L		0 - 40 mmol/L	
Sensitivity	1.5 x 10 ⁻² ΔA per mmol/L of carbon dioxide		5.2 x 10 ⁻² ΔA per mmol/L of carbon dioxide	
Precision:	Level 1	Level 2	Level 1	Level 2
Mean (mmol/L)	19.5	33.8	18.9	33.0
% CV (within-run)	1.1	1.2	2.5	1.9
% CV (total)	3.1	2.5	1.2	1.1
Accuracy:				
Sample size (n)	220		200	
Corr. Coefficient (r)	0.999		0.997	
Linear regression	1.01x - 0.8 mmol/L		1.04x + 0.4 mmol/L	

Table 4 - COBAS INTEGRA Glucose HK Liquid (GLULF)

	COBAS INTEGRA Glucose HK Liquid (GLULF) (fast application) (modification)		COBAS INTEGRA Glucose HK Liquid (GLUL) (standard application) (cleared)	
Methodology	Enzymatic reference method with hexokinase		Enzymatic reference method with hexokinase	
Sample type	Serum and plasma		Serum, plasma, urine and CSF	
Calibrator	Roche Calibrator (human) (K942706)		Roche Calibrator (human)	
Controls	Roche Control Serum N and P (human) (K972214)		Roche Control Serum N and P (human)	
Reagents	Mono reagent in vial A and B (liquid)		Mono reagent in vial A and B (liquid)	
Performance Characteristics:				
Assay range	0 - 30 mmol/L		0 - 40 mmol/L	
Sensitivity	5.4 x 10 ⁻² ΔA per mmol/L of glucose		5.4 x 10 ⁻² ΔA per mmol/L of glucose	
Precision: Mean (mmol/L)	Level 1 4.7	Level 2 27.7	Level 1 5.3	Level 2 33.2
% CV (within-run)	1.4	0.5	1.7	0.72
% CV (total)	2.4	1.2	2.6	1.5
Accuracy: Sample size (n)	216		220	
Corr. Coefficient (r)	0.999		0.999	
Linear regression	0.99x + 0.01 mmol/L		1.05x - 0.2 mmol/L	



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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

James W. Haynes
. Regulatory Affairs Associate
Roche Diagnostic Systems
1080 U.S. Highway 202
Somerville, New Jersey 08876-3771

Re: K980996
Roche COBAS® INTEGRA Carbon Dioxide Reagent Cassette and
Roche COBAS® INTEGRA Glucose HK Liquid Reagent
Regulatory Class: II
Product Code: KHS, CFR
Dated: March 16, 1998
Received: March 17, 1998

Dear Mr. Haynes:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

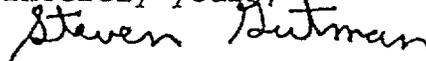
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

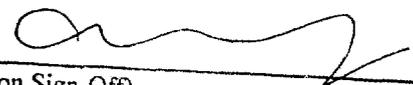
510(k) Number (if known) _____

Device Name: Roche COBAS INTEGRA Carbon Dioxide-(CO2-S) Reagent Cassette
Roche COBAS INTEGRA Glucose HK Liquid Reagent Cassette

Indications for Use:

The cassette Roche COBAS INTEGRA Carbon Dioxide (CO2-S) contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA for the quantitative determination of the carbon dioxide concentration in serum and plasma. Determination of carbon dioxide concentration in blood is most commonly performed as an initial test in the evaluation of the body's ability to control blood pH by appropriate removal of metabolism byproducts via the lung and kidneys.

The cassette Roche COBAS INTEGRA Glucose HK Liquid contains an in vitro diagnostic reagent system intended for use on the COBAS INTEGRA for the quantitative determination of the glucose concentration in serum, plasma, urine and cerebrospinal fluid (CSF). In addition, an optional glucose "fast application" for serum and plasma is available. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and idiopathic hypoglycemia.



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number N 980996

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)