



SEP 28 1998

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: K982382

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 July 7, 1998

Contact: Rita Smith
Senior Regulatory Affairs Associate
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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.

Table 1

Product Name	Classification Name	Product Code	CFR Number and Regulatory Class
COBAS INTEGRA α -1-Antitrypsin Reagent Cassette (AAT)	α -1-antitrypsin, antigen, antiserum, control	DEM	866.5130 Class II
Roche COBAS INTEGRA Immunoglobulin A Reagent Cassette (IGA/IGAP)	Immunoglobulins, (G,A,M) nephelometric methods	CFN	866.5510 Class II
Roche COBAS INTEGRA Immunoglobulin M Reagent Cassette (IGM/IGMP)	Immunoglobulins, (G,A,M) nephelometric methods	CFN	866.5510 Class II
Roche COBAS INTEGRA Immunoglobulin G Reagent Cassette (IGGT/IGGTC)	Immunoglobulins, (G,A,M) nephelometric methods	CFN	866.5510 Class II

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	Date Predicate Cleared	Predicate 510(k) Number
COBAS INTEGRA α-1-Antitrypsin Reagent Cassette (AAT)	Boehringer Mannheim α-1- Antitrypsin Reagent	1/9/98	K972640
Roche COBAS INTEGRA Immunoglobulin A Reagent Cassette (IGA/IGAP)	Boehringer Mannheim Immunoglobulin A Reagent	2/9/96	K955907
Roche COBAS INTEGRA Immunoglobulin M Reagent Cassette (IGM/IGMP)	Boehringer Mannheim Immunoglobulin M Reagent	2/9/96	K955908
Roche COBAS INTEGRA Immunoglobulin G Reagent Cassette (IGGT/IGGTC)	Boehringer Mannheim Immunoglobulin G Reagent and Behring Diagnostics Immunoglobulin G Reagent	2/9/96 2/5/80	K955906 K800119

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, which is also known as the COBAS INTEGRA 700. 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 108 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); August 12, 1997 (K972250); and May 21, 1998 (K974695).

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 modifications to four currently marketed reagent cassettes: Roche COBAS INTEGRA α -1-Antitrypsin Reagent Cassette (AAT); Roche COBAS INTEGRA Immunoglobulin A Reagent Cassette (IGA/IGAP); Roche COBAS INTEGRA Immunoglobulin M Reagent Cassette (IGM/IGMP); and Roche COBAS INTEGRA Immunoglobulin G Reagent Cassette (IGGT/IGGTC).

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

Tables 3-7 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 3-7 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.

COBAS INTEGRA α -1-Antitrypsin (AAT)

The cassette COBAS INTEGRA α -1-Antitrypsin (AAT) contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA 700 for the quantitative immunological determination of human α -1-antitrypsin in serum and plasma. The measurements aid in the diagnosis of several conditions including juvenile and adult cirrhosis of the liver. In addition, α -1-antitrypsin deficiency has been associated with pulmonary emphysema.

Table 3 - COBAS INTEGRA α -1-Antitrypsin (AAT)

	COBAS INTEGRA α-1-Antitrypsin (AAT) (modified)	COBAS INTEGRA α-1-Antitrypsin (AAT) (cleared) K954992	BM Tina-Quant α-1-antitrypsin (K972640)
Intended Use	quantitative immunological determination of α -1-antitrypsin in serum and plasma	quantitative immunological determination of α -1-antitrypsin in serum	quantitative immunological determination of α -1-antitrypsin in serum and plasma
Performance Characteristics:			
Accuracy:	serum/plasma vs. BM	serum	vs. Behring Nephelometric
Sample size (n)	288	284	123
Corr. Coefficient (r)	0.995	0.930	0.967
Linear regression	1.30x - 0.31 g/L	0.90x + 0.06 g/L	0.993x + 9.9 mg/dL

COBAS INTEGRA Immunoglobulin A (IGA/IGAP)

The cassette COBAS INTEGRA Immunoglobulin A (IGA/IGAP) contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA 700 for the quantitative immunological determination of human immunoglobulin A in serum and plasma. In addition to the standard application (IGA), the sensitive application (IGAP) is designed for the quantitative determination of low IgA concentrations in e.g. pediatric samples. Measurement of this immunoglobulin aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

Table 4 - COBAS INTEGRA Immunoglobulin A (IGA/IGAP)

	COBAS INTEGRA Immunoglobulin A (IGA/IGAP) (modified)		COBAS INTEGRA Immunoglobulin A (IGA/IGAP) (cleared) K954457		BM Tina-Quant Immunoglobulin A Assay (K955907)		
Intended Use	quantitative immunological determination of human immunoglobulin A in serum and plasma, and sensitive application for the quantitative determination of low IgA concentration in e.g. pediatric samples		quantitative immunological determination of human immunoglobulin A in serum, and sensitive application for the quantitative determination of low IgA concentration in e.g. pediatric samples		quantitative determination of IgA in serum and plasma on automated clinical chemistry analyzers.		
Affected Parameters:							
Predilution Factor	21		41				
Postdilution Factor	13.5		2.4				
Sample Volume	5 uL		9 uL				
R1 + water volume	90 uL + 10 uL		90 uL				
R2 + water volume	5 uL + 5 uL		9 uL				
First Calc. Cycle	T0		19				
IGA Performance Characteristics:							
Precision:	Level 1	Level 2	Level 1	Level 2	Level 1	Level 2	Level 3
Mean	2.0 (g/L)	6.2 (g/L)	2.3 (g/L)	3.5 (g/L)	118.8 (mg/dL)	227.7 (mg/dL)	268.5 (mg/dL)
CV (%) within-run	2.0	0.97	1.4	0.81	0.9	0.8	1.0
CV (%) total	2.3	1.2	2.8	1.8	2.2	1.8	2.1
Accuracy:	vs. BM/Hitachi				vs. Behring Nephelometric		
Sample size (n)	584		400		36		
Corr. Coefficient (r)	0.994		0.989		0.99		
Linear regression	1.023 x - 0.214 g/L		0.97 x - 0.05 g/L		0.83x + 20.6 mg/dL		
Assay Range	0.45 - 7.3 g/L 0.15 - 98.6 g/L (with rerun)		0.79 - 12.6 g/L 0.27 - 30.2 g/L (with rerun)		50 mg/dL - highest calibrator 20 - 6000 mg/dL (with rerun)		
Sensitivity	0.45 g/L		0.79 g/L		20 mg/dL		

COBAS INTEGRA Immunoglobulin M (IGM/IGMP)

The cassette COBAS INTEGRA Immunoglobulin M (IGM/IGMP) contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA 700 for the quantitative immunological determination of human immunoglobulin M in serum and plasma. In addition to the standard application (IGM), the sensitive application (IGMP) is designed for the quantitative determination of low IgM concentrations in e.g. pediatric samples. Measurement of this immunoglobulin aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

Table 5 - COBAS INTEGRA Immunoglobulin M (IGM/IGMP)

	COBAS INTEGRA Immunoglobulin M (IGM/IGMP) (modified)	COBAS INTEGRA Immunoglobulin M (IGM/IGMP) (cleared) K954457	BM Tina-Quant Immunoglobulin M Assay (K955908)
Intended Use	quantitative immunological determination of human immunoglobulin M in serum and plasma, and sensitive application for the quantitative determination of low IgM concentration in e.g. pediatric samples	quantitative immunological determination of human immunoglobulin M in serum, and sensitive application for the quantitative determination of low IgM concentration in e.g. pediatric samples	For the quantitative determination of IgM in serum and plasma on automated clinical chemistry analyzers
Affected Parameters: Calibrator dilution ratio Predilution Factor Postdilution Factor Sample Volume R1 + water volume R2 First Calc. Cycle	1:3, 1:6, 1:12, 1:24, 1:48, 1:96 21 4.7 13 uL 65 uL + 20 uL 13 uL T0	1:6, 1:12, 1:24, 1:48, 1:96 41 2.4 26 uL 65 uL + 10 uL 16 uL 19	
IGM Performance Characteristics:			
Precision: Mean	Level 1 0.55 (g/L)	Level 2 2.0 (g/L)	Level 1 0.6 (g/L)
CV (%) within-run	2.4	1.6	2.6
CV (%) total	3.2	1.9	3.1
Accuracy: Sample size (n) Corr. Coefficient (r) Linear regression	vs. BM/Hitachi 556 0.994 1.293 x + 0.341 g/L	400 0.994 1.12 x - 0.06 g/L	vs. Behring Nephelometric 39 0.979 0.81x + 5.9 mg/dL
Assay Range	0.16 - 5.18 g/L 0.05 - 24.35 g/L (with rerun)	0.31 - 5.0 g/L 0.11 - 12.1 g/L (with rerun)	25 mg/dL - highest calibrator 10 - 4000 mg/dL (with rerun)
Sensitivity	0.16 g/L	0.31 g/L	10 mg/dL



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 28 1998

Ms. Rita Smith
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Roche Diagnostic System, Inc.
a subsidiary of Hoffmann-La Roche, Inc.
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1080 U.S. Highway 202
Somerville, New Jersey 08876-3771

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Re: K982382
Trade Name: Roche COBAS® INTEGRA Reagent Cassettes
Regulatory Class: II
Product Code: DEM, CFN, DAH, CZP, DEW
Dated: July 7, 1998
Received: July 8, 1998

Dear Ms. Smith:

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 legally marketed predicate 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 (Premarket 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 premarket 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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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/dsma/dsmamain.html>".

Sincerely yours,

Steven Gutman

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) K982382

Device Name: Roche COBAS INTEGRA α -1-Antitrypsin Reagent Cassette (AAT)
Art. No. 07 5092 1

Roche COBAS INTEGRA Immunoglobulin A Reagent Cassette
(IGA/IGAP) Art. No. 07 3775 5

Roche COBAS INTEGRA Immunoglobulin M Reagent Cassette
(IGM/IGMP) Art. No. 07 3777 1

Roche COBAS INTEGRA Immunoglobulin G Reagent Cassette
(IGGT/IGGTC) Art. No. 07 6663 1

Indications for Use:

The cassette COBAS INTEGRA α -1-Antitrypsin (AAT) contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA 700 for the quantitative immunological determination of human α -1-antitrypsin in serum and plasma. The measurements aid in the diagnosis of several conditions including juvenile and adult cirrhosis of the liver. In addition, α -1-antitrypsin deficiency has been associated with pulmonary emphysema.

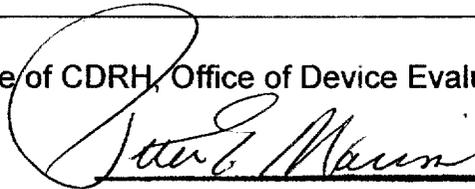
The cassette COBAS INTEGRA Immunoglobulin A (IGA/IGAP) contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA 700 for the quantitative immunological determination of human immunoglobulin A in serum and plasma. In addition to the standard application (IGA), the sensitive application (IGAP) is designed for the quantitative determination of low IgA concentrations in e.g. pediatric samples. Measurement of this immunoglobulin aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

The cassette COBAS INTEGRA Immunoglobulin M (IGM/IGMP) contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA 700 for the quantitative immunological determination of human immunoglobulin M in serum and plasma. In addition to the standard application (IGM), the sensitive application (IGMP) is designed for the quantitative determination of low IgM concentrations in e.g. pediatric samples. Measurement of this immunoglobulin aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

The cassette COBAS INTEGRA Immunoglobulin G (Turbidimetric) (IGGT/IGGTC) contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA 700 for the quantitative immunological determination of human immunoglobulin G in serum, plasma (IGGT) and cerebrospinal fluid (IGGTC). Measurement of this immunoglobulin aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

Prescription Use ✓
(Per 21 CFR 801.109)

OR

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