

OCT 21 1998

510(k) Summary

Introduction According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact Boehringer Mannheim Corporation, dba Roche Diagnostics
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: Luann Ochs

Date Prepared: September 18, 1998

2) Device name Proprietary name: Roche Diagnostics Magnesium Reagent

Common name: magnesium test system

Classification name: photometric method, magnesium 75JGJ
Device Class I

3) Predicate device We claim substantial equivalence to the currently marketed Roche Diagnostics Magnesium reagent system, catalog number 804551, manufactured by Bio-Analytical labs. K810084.

4) Device Description Magnesium, in the presence of EGTA, is coupled with xylidyl blue in an alkaline solution.

Magnesium + xylidyl blue $\xrightarrow{\text{alkaline}}$ purple complex

EGTA in the reagent complexes with calcium, so that only magnesium reacts with the indicator. The intensity of the color of the purple complex formed is proportional to the magnesium concentration and can be measured photometrically.

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510(k) Summary, Continued

5) Intended use The Roche Diagnostics Magnesium reagent is intended for use for the quantitative determination of magnesium in human serum, plasma, and urine on automated clinical chemistry analyzers.

6) Comparison to predicate device The Roche Diagnostics Magnesium reagent is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Roche Diagnostics Magnesium reagent system, catalog number 804551, manufactured by Bio-Analytical Labs, K810084.

The following table illustrates the similarities between the Roche Diagnostics Magnesium Reagent and the predicate device. Specific data on the performance of the system have been incorporated into the draft labeling in Section V of this submission. Labeling for the predicate device is provided in Section VI.

Similarities:

Feature	New Magnesium Reagent	Predicate Magnesium Reagent
Intended Use	Measurement of magnesium	Measurement of magnesium
Sample Type	Serum, plasma, CSF, no preparation required. Urine, diluted with 0.9% saline or water	Serum, plasma, CSF, no preparation required. Urine, acidified to pH 1 prior to assay
Use on Automated Chemistry Analyzers?	Yes	Yes
Test Principle	Magnesium is reacted with xylydyl blue in an alkaline solution, in the presence of EGTA, resulting color is measured spectrophotometrically	Magnesium is reacted with calmagite in an alkaline solution, in the presence of EGTA and KCN, resulting color is measured spectrophotometrically
Calibration	Two points, blank (saline) and about 1.4 mmol/L (2.8 mEq/L)magnesium	Two points, blank (saline) and about about 1.4 mmol/L (2.8 mEq/L)magnesium

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510(k) Summary, Continued

6) Comparison to predicate device (continued)

Similarities:

Feature	New Magnesium Reagent	Predicate Magnesium Reagent
Calibration Stability	Perform a new calibration with a bottle or reagent lot change	Perform a new calibration every 24 hours, and with a bottle or reagent lot change
Kit Configuration, Reagent Preparation	R1, liquid, ready-to-use R2, liquid, ready-to-use	R1, liquid, ready-to-use R2, liquid, ready-to-use
Reagent On-board Stability	3 weeks	1 week

6) Comparison to predicate device, continued

Differences:

There are no significant differences between the Roche Diagnostics Magnesium reagent and the predicate device for purposes of considering substantial equivalence.

Performance characteristics:

The performance of the Roche Diagnostics Magnesium reagent is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Roche Diagnostics Magnesium reagent system, catalog number 804551, manufactured by Bio-Analytical Labs, K810084.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 21 1998

Luann Ochs
• Regulatory Program Manager
Boehringer Mannheim Corporation, dba Roche Diagnostics
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K983416
Roche Diagnostics Magnesium Reagent
Regulatory Class: I
Product Code: JGJ
Dated: September 18, 1998
Received: September 29, 1998

Dear Ms. Ochs:

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 (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.

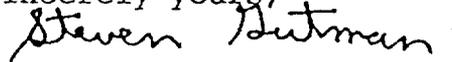
Page 2

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): K 983416
Device Name: Roche Diagnostics Magnesium Reagent

Indications for Use:

The Roche Diagnostics Magnesium reagent is intended for use for the quantitative determination of magnesium in human serum, plasma, and urine on automated clinical chemistry analyzers.

According to the Code of Federal Regulations, Title 21 (Food and Drugs), Part 862.1495, a Magnesium test system is a device intended to measure magnesium levels in serum and plasma. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium). It is classified in Class I.

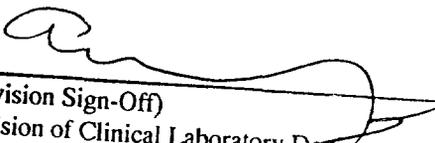
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 98 3416