

DEC 1 1998

**510(k) Summary**

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**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.

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

Contact Person: Jennifer Tribbett

Date Prepared: September 25, 1998

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**2) Device name** Proprietary name: Roche Diagnostics, Boehringer Mannheim Inorganic Phosphorus Reagent

Common name: Phosphorus (inorganic) test system

Classification name: Phosphomolybdate (colorimetric), Inorganic Phosphorus, 75CEO  
Device Class I

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**3) Predicate device** We claim substantial equivalence to the currently marketed Roche Diagnostics, Boehringer Mannheim Phosphorus (inorganic) test system.

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**4) Device Description** Endpoint method with sample blanking.

Inorganic phosphate forms an ammonium phosphomolybdate complex with ammonium molybdate in the presence of sulfuric acid. The complex is determined photometrically in the ultraviolet region (340 nm).

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## 510(k) Summary, Continued

5) **Intended use** The Roche Diagnostics, Boehringer Mannheim Inorganic Phosphorus Reagent is intended for the quantitative in vitro determination of phosphorus in human serum, plasma and urine with automated clinical chemistry analyzers.

6) **Substantial equivalence - Similarities** The Roche Diagnostics, Boehringer Mannheim Phosphorus (inorganic) 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, Boehringer Mannheim Phosphorus (inorganic) reagent.

The following table illustrates the similarities between the Roche Diagnostics, Boehringer Mannheim Phosphorus (inorganic), extended claims reagent system and the currently marketed Phosphorus (inorganic) reagent system. Specific data on the performance of the system have been incorporated into the draft labeling in Section V of this submission. The insert for the currently marketed phosphorus reagent is provided in Section VI .

<b>Feature</b>	<b>Modified Phosphorus Reagent Insert</b>	<b>Current Phosphorus Reagent Insert</b>
Intended Use	Measurement of inorganic phosphorus	Same
Test Principle	Sample blank endpoint method. Inorganic phosphate forms an ammonium phosphomolybdate complex with ammonium molybdate in the presence of sulfuric acid. The complex is determined photometrically in the ultraviolet region (340 nm).	Same

*Continued on next page*

## 510(k) Summary, Continued

### Substantial equivalence – Similarities, continued

Limitations-Interferences	<p>Icterus: No significant interference from bilirubin (conjugated or unconjugated) up to an I index of 60</p> <p>Hemolysis: RBC contamination elevates results.</p> <p>Lipemia (Intralipid): No significant interference from lipemia up to an L index of 1000</p>	Same
Kit Configuration, Reagent Preparation	<p>R1 Reagent Blank (Ready to Use)</p> <p>R2 Phosphate Reagent (Ready to Use)</p>	Same

### 6) Substantial equivalence - differences

#### Differences:

The claims for specimen collection, reportable range (urine), imprecision and method comparison (urine) have been extended.

#### Performance characteristics:

The data related to these claims is described in section VI . Based on the data, we believe that the extended claims continue to support substantial equivalence to other products in commercial distribution intended for similar use.



DEC 1 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Jennifer L. Tribbett  
Regulatory Affairs Consultant  
Boehringer Mannheim Corp.  
9115 Hague Road  
P.O. Box 50457  
Indianapolis, IN 46250

Re: K983503  
Trade Name: Roche Diagnostics, Boehringer Mannheim Corporation  
Inorganic Phosphorus  
Regulatory Class: I  
Product Code: CEO  
Dated: October 2, 1998  
Received: October 6, 1998

Dear Ms. Tribbett:

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 (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 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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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 at (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 983503

Device Name: Roche Diagnostics, Boehringer Mannheim Inorganic Phosphorus Reagent

Indications for Use:

The Roche Diagnostics, Boehringer Mannheim Inorganic Phosphorus reagent is intended for use for the quantitative in vitro determination of phosphorus in human serum, plasma and urine with automated clinical chemistry analyzers.

According to the Code of Federal Regulations, Title 21 (Food and Drugs), Part 862.1580, a Phosphorus (inorganic) test system is a device intended to measure inorganic phosphorus in serum, plasma, and urine. Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

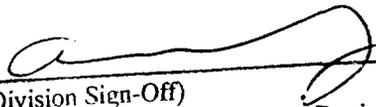
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

  
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(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K 983503