

K972639

**BOEHRINGER  
MANNHEIM  
CORPORATION**

JAN - 9 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** Boehringer Mannheim Corporation  
135 Sandberg Street  
Thousand Oaks, CA 91360  
(805) 241 - 7575

Contact Person: Mary Koning

Date Prepared: July 13, 1997

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**2. Device name** Proprietary name: Tina-quant® Haptoglobin Assay  
Common name: Immunoturbidometric assay for the determination of Haptoglobin.

Classification name: Haptoglobin immunological test system

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**3. Predicate device** The Boehringer Mannheim Tina-quant® Haptoglobin is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Behring BN® Haptoglobin assay.

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## 510(k) Summary, Continued

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**4.  
Device  
Description**

The Haptoglobin determination is based upon turbidimetric immunoinhibition (TINIA) using a serum or plasma blood sample. The sample containing Haptoglobin is transferred into a TRIS buffer solution (R<sub>1</sub> reagent). In the second step, an aliquot of solution of polyclonal anti-human Haptoglobin antibodies (R<sub>2</sub> reagent) is added to mixture of the first step. The antibody will bind to the Haptoglobin in the sample to form "aggregates" such that the amount of aggregate formed is proportionate to the amount of Haptoglobin present in the sample.

The resulting agglutination complex is measured turbidimetrically whereby increased turbidity is reflected through an increase in optical density. Therefore, the amount of Haptoglobin in the sample is directly proportional to the amount of turbidity formed.

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**5.  
Intended use**

Immunoturbidometric assay for the quantitative in-vitro determination of Haptoglobin.

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**6.  
Comparison  
to predicate  
device**

The Boehringer Mannheim Tina-quant® Haptoglobin is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Behring BN® Haptoglobin assay.

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**510(k) Summary, Continued**

**6. Comparison to predicate device cont.**

The following table compares the Tina-quant® Haptoglobin with the predicate device, Behring BN® Haptoglobin assay. Specific data on the performance of the test have been incorporated into the draft labeling in attachment 5. Labeling for the predicate device is provided in attachment 6.

**Similarities:**

- Intended Use: Immunoassay for the in vitro quantitative determination of Haptoglobin
- Sample type: Serum and plasma

**Differences:**

Feature	Tina-quant® Haptoglobin	Behring BN® Haptoglobin
Reaction test principle	Immunoturbidimetric	Latex bound antigen/antibody causing visible agglutination through large immune complex formation.
Instrument required	Hitachi	Behring Nephelometer (BN)

**Performance Characteristics:**

Feature	Tina-quant® Haptoglobin			Behring BN® Haptoglobin
Precision	Intra and InterAssay (ng/ml):			Intra and InterAssay (mg/dL):
Level	<u>Pool</u>	<u>Low</u>	<u>High</u>	
N	21	21	21	30
Intra-Assay Mean	167.1	124.9	280.5	188
%CV	2.5	3.0	2.1	2.5
Level	<u>Sample 1</u>		<u>Sample 2</u>	
N	21		21	10
Inter-Assay Mean	27.9		123.3	185
%CV	2.0		1.9	3.0
Lower Detection Limit	5 mg/dL			---

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**510(k) Summary, Continued**

**6. Comparison to predicate device, (cont.)**

**Performance Characteristics:**

<b>Feature</b>	<b>Tina-quant® Haptoglobin</b>	<b>Behring BN®Haptoglobin</b>
Linearity	20 - 570 mg/dL	---
Method Comparison	Vs Behring BN® Haptoglobin <u>Deming's</u> $y = 0.998x + 2.7$ $r = 0.982$ $SEE = 10.97$ $N = 98$  <u>Least Squares:</u> $y = 0.981x + 5.5$ $r = 0.982$ $SEE = 15.36$ $N = 98$	Vs Partigen® Haptoglobin  <u>Linear Regression</u> $y = 1.01x - 11$ $r = 0.96$  $N = 30$
Interfering substances	No interference at: (≤ 10% error)  Bilirubin 60 mg/dL Hemoglobin 500 mg/dL Lipemia 1500 mg/dL Rheumatoid Factor 2000 IU/mL	---
Specificity	Specific for haptoglobin	Specific for haptoglobin

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Mary Koning  
Regulatory Affairs Specialist  
Boehringer Mannheim Corporation  
135 Sandberg Street  
Thousand Oaks, California 91360

JAN - 9 1998

Re: K972639/S1  
Trade Name: Tina-quant® Haptoglobin Assay  
Regulatory Class: II  
Product Code: DAD  
Dated: October 20, 1997  
Received: October 22, 1997

Dear Ms. Koning:

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 requirement, 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.

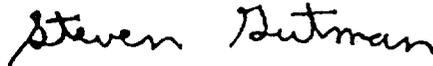
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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

