

JAN - 9 1998

K972638

**BOEHRINGER  
MANNHEIM  
CORPORATION**



## 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  
135 Sandberg Street  
Thousand Oaks, CA 91360  
(805) 241 - 7575

Contact Person: Mary Koning

Date Prepared: July 13, 1997

### 2. Device name

Proprietary name: Tina-quant® Prealbumin Assay

Common name: Immunoturbidometric assay for the determination of Prealbumin.

Classification name: Prealbumin immunological test system

### 3. Predicate device

The Boehringer Mannheim Tina-quant® Prealbumin 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® Prealbumin assay.

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## 510(k) Summary, Continued

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**4.  
Device  
Description**

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

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**5.  
Intended use**

Immunturbidometric assay for the quantitative in-vitro determination of Prealbumin.

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**6.  
Comparison  
to predicate  
device**

The Boehringer Mannheim Tina-quant® Prealbumin 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® Prealbumin assay.

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## 510(k) Summary, Continued

6. **Comparison to predicate device cont.** The following table compares the Tina-quant® Prealbumin with the predicate device, Behring BN® Prealbumin 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 Prealbumin
- Sample type: Serum and plasma

### Differences:

Feature	Tina-quant® Prealbumin	Behring BN® Prealbumin
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® Prealbumin			Behring BN® Prealbumin
Precision	Intra and InterAssay (mg/dL):			Intra and InterAssay (mg/dL):
Level	<u>Low</u>	<u>Sample</u>	<u>High</u>	
N	21	21	21	30
Intra-Assay Mean	27.8	30.1	58.7	36.2
%CV	3.6	3.0	2.4	1.0
Level	<u>Sample 1</u>		<u>Sample 2</u>	
N	21		21	10
Inter-Assay Mean	26.6		28.8	35.6
%CV	2.0		1.6	1.1

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**510(k) Summary, Continued**

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

**Performance Characteristics:**

<b>Feature</b>	<b>Tina-quant® Prealbumin</b>	<b>Behring BN® Prealbumin</b>
<b>Lower Detection Limit</b>	1.5 mg/dL	---
<b>Method Comparison</b>	Vs Behring BN® Prealbumin <u>Passing/Bablok</u> $y = 1.04x + 0.1$ $r = 0.978$ SEE = 0.9 N = 102  <u>Least Squares:</u> $y = 1.04x + 0.2$ $r = 0.978$ SEE = 1.4 N = 102	Vs NDR Parigen® Prealbumin <u>Linear Regression</u> $y = 0.84x - 0.017$  SEE = 0.00 N = 40
<b>Interfering substances</b>	No interference at: (≤ 10% error)  Bilirubin 60 mg/dL Hemoglobin 500 mg/dL Lipemia 1700 mg/dL Rheumatoid Factor 2000 IU/mL	---
<b>Specificity</b>	Specific for prealbumin	Specific for prealbumin



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: K972638/S1  
Trade Name: Tina-quant® Prealbumin Assay  
Regulatory Class: I  
Product Code: JZJ  
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.

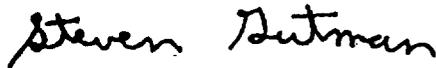
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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

510(k) Number (if known): K972638

Device Name: Tina-quant® Prcalbumin Assay

Intended use

Immunological latex agglutination test for the in vitro quantitative determination of prealbumin in human serum and plasma.

Measurement of prealbumin levels in serum may aid in the assessment of the patient's nutritional status.

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

K972638