

OCT 16 1998

## 510(k) Summary

K980724

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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  
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Pleasanton, CA 94566-0900  
(510) 730-8240  
FAX (510) 225-0654  
Contact Person: Betsy Soares-Maddox

Date Prepared: February 11, 1998

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**2. Device name** Proprietary name: Tina-quant®  $\beta$  2-microglobulin Assay  
Common name: Immunoturbidometric assay for the determination of  $\beta$  2-microglobulin.

Classification name:  $\beta$  2-microglobulin immunological test system

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**3. Predicate device** The Boehringer Mannheim Tina-quant®  $\beta$  2-microglobulin is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Abbott IMx®  $\beta$  2-microglobulin assay.

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## 510(k) Summary, Continued

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**4.  
Device  
Description**

The  $\beta$  2-microglobulin determination is based upon turbidimetric immunoinhibition (TINIA) using a serum or plasma blood sample. The sample containing  $\beta$  2-microglobulin is transferred into a TRIS buffer solution ( $R_1$  reagent). In the second step, an aliquot of solution of polyclonal anti-rabbit  $\beta$  2-microglobulin antibodies ( $R_2$  reagent) is added to mixture of the first step. The antibody will bind to the  $\beta$  2-microglobulin in the sample to form "aggregates" such that the amount of aggregate formed is proportionate to the amount of  $\beta$  2-microglobulin 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  $\beta$  2-microglobulin 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  $\beta$  2-microglobulin.

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**6.  
Comparison  
to predicate  
device**

The Boehringer Mannheim Tina-quant®  $\beta$  2-microglobulin is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Abbott IMx®  $\beta$  2-microglobulin assay.

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## 510(k) Summary, Continued

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

The following table compares the Tina-quant®  $\beta$  2-microglobulin with the predicate device, Abbott IMx®  $\beta$  2-microglobulin 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  $\beta$  2-microglobulin

**Differences:**

Feature	Tina-quant® $\beta$ 2-microglobulin	Abbott IMx® $\beta$ 2-microglobulin
Sample Type	Serum and Plasma	Serum, Plasma, and Urine
Reaction test principle	Immunoturbidimetric	Microparticle
Instrument required	Hitachi	Abbott IMx

**Performance Characteristics:**

Feature	Tina-quant® $\beta$ 2-microglobulin			Abbott IMx® $\beta$ 2-microglobulin		
Precision	Intra and InterAssay (mg/l):			Intra and InterAssay (mg/L):		
Level	<u>Low</u>	<u>Mid</u>	<u>High</u>	<u>Low</u>	<u>Mid</u>	<u>High</u>
N	21	21	21	12	12	12
Intra-Assay Mean	0.57	2.26	7.75	1.7	3.9	9.7
%CV	4.4	1.9	1.0	6.0	4.4	4.9
Level	<u>Sample 1</u>		<u>Sample 2</u>	<u>Low</u>	<u>Mid</u>	<u>High</u>
N	21		21	90	90	90
Inter-Assay Mean	1.16		4.70	1.7	3.9	9.7
%CV	2.6		2.7	9.2	6.8	7.3
Lower Detection Limit	0.05 mg/L			0.5 $\mu$ g/L		

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## 510(k) Summary, Continued

6.  
Comparison  
to predicate  
device, (cont.)

### Performance Characteristics:

Feature	Tina-quant® β 2- microglobulin	Abbott IMx® β 2- microglobulin
Linearity	0.20 - 8.0 mg/L	---
Method Comparison	Vs Abbott IMx® β 2- microglobulin <u>Deming's</u> $y = 1.26x - 0.15$ $r = 0.983$ $SEE = 0.23$ $N = 36$  <u>Least Squares:</u> $y = 1.24x - 0.11$ $r = 0.983$ $SEE = 0.32$ $N = 36$	---
Interfering substances	No interference at: (≤ 10% error)  Bilirubin 20 mg/dL Hemoglobin 500 mg/dL Lipemia 1500 mg/dL Rheumatoid Factor 200 IU/mL	---
Specificity	Specific for β 2- microglobulin	Specific for β 2- microglobulin



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 16 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Betsy Soares-Maddox  
Manager, Regulatory Affairs  
and Quality Assurance  
Boehringer Mannheim Corporation  
4300 Hacienda Drive  
P.O. Box 9002  
Pleasanton, California 94566-0900

Re: K980724/S1  
Trade Name: Tina-quant®  $\beta$  2-microglobulin Assay  
Regulatory Class: II  
Product Code: JZG  
Dated: August 31, 1998  
Received: September 1, 1998

Dear Ms. Soares-Maddox:

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.

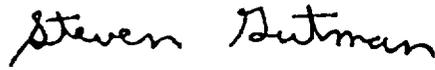
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S'.

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): N/A K980724

Device Name: Tina-quant® β 2-microglobulin Assay

Indications For Use:

Intended use

Immunological latex agglutination test for the in vitro quantitative determination of β 2-microglobulin in human serum and plasma.

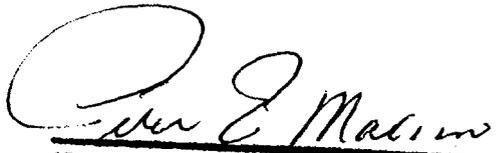
Measurement of *beta*-2-microglobulin aids in the diagnosis of active rheumatoid arthritis and kidney disease.

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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** \_\_\_\_\_