

## 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  
9115 Hague Rd  
Indianapolis, IN 46250  
(317) 845-3723

Contact person: Priscilla A. Hamill

Date prepared: September 8, 1997

---

**2) Device name** **Proprietary name:** Boehringer Mannheim Tina-quant ® IgE Test

**Common name:** IgE

**Classification name:** Immunoglobulins A, G, M, D, and E immunological test system

---

**3) Predicate device** We claim substantial equivalence to the Behring N IgE test

---

**4) Device description** The Boehringer Mannheim Tina-quant ® IgE test is based on the principle of immunological agglutination with enhanced of the reaction by latex.

---

**5) Intended use** The Boehringer Mannheim Tina-quant ® IgE test is intended for the quantitative in vitro determination of IgE in serum and plasma on automated clinical chemistry analyzers.

---

*Continued on next page*

## 510(k) Summary, Continued

- 6) **Comparison to the predicate device** The Boehringer Mannheim Tina-quant ® IgE Test is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Behring N IgE test.

### Similarities:

#### Similarities

The following table compares Boehringer Mannheim ® IgE Test with the predicate device. 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

Feature	Boehringer Mannheim Tina-quant ® IgE Test	Behring N IgE Test
Intended use	For the quantitative determination of IgE in human serum and plasma on automated clinical chemistry analyzers	For the quantitative determination of IgE in human serum and plasma on automated clinical chemistry analyzers
Indications for use	An aid in the diagnosis of allergic diseases	An aid in the diagnosis of allergic diseases
Sample type	Human serum, plasma	Human serum, plasma
Assay reaction principle	Particle-enhanced immunological agglutination	Particle-enhanced immunological agglutination
Standard-ized against	WHO Standard	WHO Standard

*Continued on next page*

## 510(k) Summary, Continued

---

### Differences

**Differences:** The following differences between Boehringer Mannheim Tina-quant ® IgE Test and the predicate device are not significant for purposes of determining substantial equivalence.

<b>Feature</b>	<b>Boehringer Mannheim Tina-quant ® IgE Test</b>	<b>Behring N Latex IgE Test</b>
Measurement approach	Photometric	Nephelometric
Instrument required	Boehringer Mannheim / Hitachi automated clinical analyzer	Behring Nephelometer
Reagent Formulation	Liquid; ready to use	Lyophilized; reconstitution required

---

### 6) Comparison to predicate device (cont.)

**Performance characteristics:** The performance of the Boehringer Mannheim Tina-quant ® IgE Test is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Behring N IgE test.

---



NOV 12 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Priscilla A. Hamill  
Regulatory Affairs Consultant  
Roche Diagnostics/Boehringer  
Mannheim Corporation  
9115 Hague Road  
Indianapolis, Indiana 46250

Re: K983185  
Trade Name: Boehringer Mannheim Tina-quant® IgE Test  
Regulatory Class: II  
Product Code: DGC  
Dated: September 8, 1998  
Received: September 11, 1998

Dear Ms. Hamill:

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.

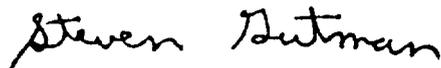
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2

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): K983185

Device Name: Boehringer Mannheim Tina-quant ® IgE Test

Indications for Use: For the quantitative in vitro determination of IgE in human serum and plasma on automated clinical chemistry analyzers. IgE determinations are used as an aid in the diagnosis of allergic diseases.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IS NEEDED)

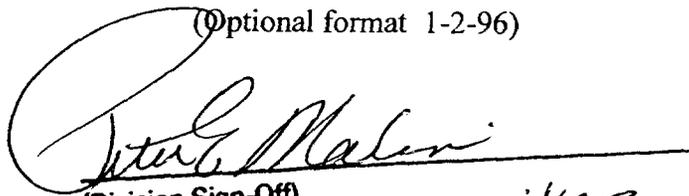
-----  
Concurrence of CDRH, Office of Device Evaluation (ODE)

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 K983185  
510(k) Number \_\_\_\_\_