



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Yvette Lloyd  
BOEHRINGER MANNEHEIM CORPORATION  
2400 Bisso Lane  
P.O. Box 4117  
Concord, CA 94524-4117

JUL 30 1997

Re: K964282/S002  
Trade Name: Tina-quant® Ferritin Assay  
Regulatory Class: II  
Product Code: JMG  
Dated: April 28, 1997  
Received: May 1, 1997

Dear Ms. Lloyd:

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.

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

8 964282

JUL 30 1997

**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  
2400 Bisso Lane  
P.O. Box 4117  
Concord, CA 94524-4117  
(510) 674 - 0690, extension 8413

Contact Person: Yvette Lloyd

Date Prepared: October 17, 1996

**2.  
Device name**

Proprietary name: Tina-quant® Ferritin Assay

Common name: Immunoturbidometric assay for the determination of Ferritin.

Classification name: Ferritin immunological test system

**3.  
Predicate  
device**

The Boehringer Mannheim Tina-quant® Ferritin is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Enzymun-Test® Ferritin assay (K860137).

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**4.  
Device  
Description**

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

**5.  
Intended use**

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

**6.  
Comparison  
to predicate  
device**

The Boehringer Mannheim Tina-quant® Ferritin is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Enzymun-Test® Ferritin assay (K860137).

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

The following table compares the Tina-quant® Ferritin with the predicate device, Enzymun-Test® Ferritin 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 Ferritin

- Sample type: Serum and plasma

**Differences:**

Feature	Tina-quant® Ferritin	Enzymun-Test® Ferritin
Reaction test principle	Immunoturbidimetric	ELISA/1-step sandwich assay with streptavidin technology
Instrument required	Hitachi	ES 300
Calibration	NIBSC standard 80/602 and 80/578 (human liver and spleen)	NIBSC standard 80/602 (human liver)

**Performance Characteristics:**

Feature	Tina-quant® Ferritin			Enzymun-Test® Ferritin			
Precision	Intra and InterAssay (ng/mL):			Modified NCCLS (ng/mL):			
	Level	<u>Low</u>	<u>Mid</u>	<u>High</u>	<u>Low</u>	<u>Mid</u>	<u>High</u>
Intra-Assay	N	21	21	21	120	120	120
	Mean	31.9	144.4	645.1	10.4	368.8	821.5
	%CV	3.8	1.4	1.1	6.2	2.7	2.5
Inter-Assay	Level	<u>Sample 1</u>		<u>Sample 2</u>			
	Mean	76.4		347.4	10.4	368.8	821.5
	%CV	2.6		2.2	6.4	4.3	4.9

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6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	Tina-quant® Ferritin	Enzymun-Test® Ferritin
Lower Detection Limit	3 ng/mL	1.0 ng/mL
Linearity	3 - 800 ng/mL	1.0 - 1000 ng/mL
Method Comparison	Vs Enzymun-Test® Ferritin <u>Passing/Bablok</u> $y = 1.04x + 4.8$ $r = 0.996$ SEE = 13.68 N = 44  <u>Least Squares:</u> $y = 1.00x + 13.1$ $r = 0.997$ SEE = 13.52 N = 44	Vs Enzymun-Test® Ferritin <u>Passing/Bablok</u> $y = 1.15x - 2.8$ $r = 0.992$ SEE = 44.9 N = 56

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6.  
 Comparison  
 to predicate  
 device, (cont.)

**Performance Characteristics:**

<b>Feature</b>	<b>Tina-quant® Ferritin</b>	<b>Enzymun-Test® Ferritin</b>
<b>Interfering substances</b>	No interference at: (≤ 10% error)	No interference at: (≤ 10% error)
Bilirubin	68 mg/dL	64.5 mg/dL
Hemoglobin	500 mg/dL	1 g/dL
Lipemia	1500 mg/dL	1250 mg/dL
Rheumatoid Factor	100 IU/mL	N/A
<b>Specificity</b>	Liver Ferritin 114.6% Spleen Ferritin 112.0% Heart Ferritin 1.7%	Liver Ferritin 100% Spleen Ferritin 89%

510(k) Number (if known): K964282

Device Name: Tinaquant Ferritin Assay

Indications For Use:

Immunological in vitro immunoturbidometric test for the quantitative determination of ferritin in human serum and plasma using clinical-chemistry analyzers.

A variety of methods are available for determining ferritin, e.g. radio-immunoassay (RIA), enzyme-linked immunosorbent assay (ELISA), fluorescence immunoassay (FIA) luminescence immunoassay (LIA) and nephelometric immunoassay.

The assay is unaffected by icterus (bilirubin up to 60 mg/dl), hemolysis (Hb < 0.5 g/dl), lipemia (triglycerides < 1500 mg/dl) and rheumatoid factor (< 100 IU/ml).  
(Criterion: recovery within ± 10% of initial value.)

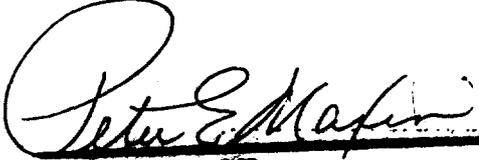
For diagnostic purposes, the ferritin findings should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

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 of Clinical Laboratory Devices  
510(k) Number \_\_\_\_\_