

JUL 28 1997

K972513

**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
Fax: (510) 687-1850

Contact Person: Yvette Lloyd

Date Prepared: July 2, 1997

2. Device name Proprietary name: Tina-quant® Myoglobin Assay

Common name: Immunoturbidometric assay for the determination of Myoglobin.

Classification name: Myoglobin immunological test system

3. Predicate device The Boehringer Mannheim Tina-quant® Myoglobin 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 Latex Myoglobin Assay.

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**4. Device
Description**

The myoglobin determination is based upon turbidimetric immunoinhibition (TINIA) using a serum or plasma blood sample. The sample containing myoglobin is transferred into a EDTA/glycine buffer solution (R₁ reagent). In the second step, an aliquot of solution containing fine latex particles coated with polyclonal anti-human myoglobin antibodies (R₂ reagent) is added to mixture of the first step. The antibody-coated particles will bind to the myoglobin in the sample to form "aggregates" such that the amount of aggregate formed is proportionate to the amount of myoglobin 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 myoglobin 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 myoglobin.

6.
Comparison to predicate device

The Boehringer Mannheim Tina-quant® Myoglobin 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 Latex Myoglobin Assay (K902154).

The following table compares the Tina-quant® Myoglobin with the predicate device, Behring Nephelometer Myoglobin 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 Myoglobin
- Sample type: Serum and plasma
- Product performance

Continued on next page



6. Comparison to predicate device cont.

Differences:

Feature	Tina-quant® Myoglobin	N Latex Myoglobin
Reaction test principle	Spectrophotometric 570 nm	Nephelometry
Instrument required	Hitachi 911	Nephelometer

Performance Characteristics:

Feature	Tina-quant® Myoglobin	N Latex Myoglobin
Precision	Intra-Assay Precision (ng/mL):	Modified NCCLS:
Level	<u>Control 1</u> <u>Control 2</u> <u>Control 3</u>	Within run Precision(µg/L)
N	20 20 20	<u>Low</u> <u>Mid</u> <u>High</u>
Mean	32.3 71.3 471.5	20 20 20
SD	0.8 0.6 1.6	85 160 310
%CV	2.6 0.9 0.3	2.0 2.4 2.9
	Inter-Assay Precision (ng/mL):	Day to Day Precision (µg/L):
	<u>Sample 1</u> <u>Sample 2</u>	<u>Low</u> <u>Mid</u> <u>High</u>
N	20 20	15 15 15
Mean	71.3 471.5	85 160 310
SD	0.6 1.6	4.8 4.2 5
%CV	0.9 0.3	

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6.
 Comparison
 to predicate
 device, (cont.)

Performance Characteristics:

Feature	Tina-quant® Myoglobin	N Latex Myoglobin
Lower Detection Limit	3.0 ng/mL	25 µg/L
Linearity	3.0 - 560 ng/mL	25.0 - 400 µg/L
Method Comparison	Vs N Latex® Myoglobin <u>Least Squares</u> $y = 1.06x + 0.35$ $r = 0.989$ SEE = 19.61 N = 41 <u>Passing/Bablok</u> $y = 1.07x + 3.6$ $r = 0.989$ SEE = 13.61 N = 41	Vs Radioimmunoassay Myoglobin <u>Least Squares</u> $y = 0.95x - 4.33$

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6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	Tina-quant® Myoglobin	N Latex Myoglobin
Interfering substances	No interference at:	
Bilirubin	60 mg/dL	No interference
Hemoglobin	0.5 g/dL	No interference
Lipemia	1500 mg/dL	No interference
Rheumatoid Factor	100 IU/mL	<3000 IU/ml
Specificity	% Cross-reactivity	% Cross-reactivity
Human cardiac myoglobin	102.4%	N/A
Human skeletal myoglobin	99.7%	N/A
Hemoglobin	0.0	N/A
Human IgG	0.0	N/A
Human Serum Albumin	0.0	N/A



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Yvette R. Lloyd
Regulatory Affairs Specialist
Boehringer Mannheim Corporation
2400 Bisso Lane
P.O. Box 4117
Concord, California 94524-4117

JUL 28 1997

Re: K972513
Tina-quant® Myoglobin Assay
Regulatory Class: II
Product Code: DDR
Dated: July 2, 1997
Received: July 7, 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 (Pre-market 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 pre-market 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.

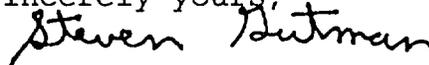
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 (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): N/A

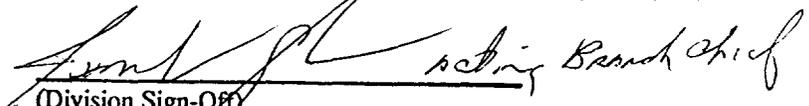
Device Name: Tina-quant® Myoglobin Assay

Indications For Use:

The Tina-quant® Myoglobin Assay is an immunoturbidometric assay for the quantitative determination of Myoglobin in serum and plasma using automated clinical chemistry analyzers. Measurement of myoglobin aids in the rapid diagnosis of heart and renal disease.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K972513

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)