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K972640

BOEHRINGER MANNHEIM CORPORATION

JAN - 9 1998

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® α -1-Antitrypsin Assay

Common name: Immunoturbidometric assay for the determination of α -1-antitrypsin.

Classification name: α -1-antitrypsin immunological test system

3. Predicate device

The Boehringer Mannheim Tina-quant® α-1-Antitrypsin 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® α-1-Antitrypsin assay.

Continued on next page

510(k) Summary, Continued

4. Device Description

The α -1-antitrypsin determination is based upon turbidimetric immunoinhibition (TINIA) using a serum or plasma blood sample. The sample containing α -1-antitrypsin is transferred into a TRIS buffer solution (R_1 reagent). In the second step, an aliquot of solution of polyclonal anti-human α -1-antitrypsin antibodies (R_2 reagent) is added to mixture of the first step. The antibody will bind to the α -1-antitrypsin in the sample to form "aggregates" such that the amount of aggregate formed is proportionate to the amount of α -1-antitrypsin 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 α-1-antitrypsin in the sample is directly proportional to the amount of turbidity formed.

5. Intended use

Immunoturbidometric assay for the quantitative in-vitro determination of α -1-antitrypsin.

6. Comparison to predicate device

The Boehringer Mannheim Tina-quant® α -1-antitrypsin 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® α -1-Antitrypsin assay.

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6. Comparison to predicate device cont.

The following table compares the Tina-quant® α-1-Antitrypsin with the predicate device, Behring BN® α -1-Antitrypsin 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 α -1-antitrypsin
- Sample type: Serum and plasma

Differences

Feature	Tina-quant® α-1-Antitrypsin	Behring BN® α -1-Antitrypsin
Reaction test principle	Immunoturbidimetric	Latex bound antigen/antibody causing visible agglutination throught large immune complex formation.
Instrument required	Hitachi	Behring Nephelometer (BN)

Performance Characteristics:

Feature	Tina-quant® α-1-Antitrypsin			Behring BN® α -1-Antitrypsin
Precision	Intra and InterAssay (mg/dl):			Within and Between (mg/dL):
Level	Low	Pool	High	
N	21	21	21	700
Intra-Assay Mean	155.7	167.1	311.9	244
%CV	3.1	2.5	2.5	3.7
Level	Sample 1	Sample 2		
Inter-Assay Mean	160.7	307.3		244
%CV	2.1	2.0		5.3

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6. Comparison to predicate device, (cont.)

Performance Characteristics:

Feature	Tina-quant® α-1-Antitrypsin	Behring BN® α -1-Antitrypsin
Lower Detection Limit	10 mg/dL	- 30 mg/dL
Method Comparison	Vs Behring BN® α -1-Antitrypsin Passing/Bablok y =0.993x + 9.9 r=0.967 SEE =9.7 N=123 Least Squares: y = 0.971x + 12.2 r = 0.967 SEE = 11.4 N = 123	Vs Behring LN® α -1-Antitrypsin Linear Regression y =0.88x + 30.2 r=0.967 N=59
Interfering substances Bilirubin Hemoglobin Lipemia Rheumatoid Factor	No interference at: (≤ 10% error) 60 mg/dL 1000 mg/dL 1000 mg/dL 100 IU/mL	N/A
Specificity	Specific for α -1-antitrypsin	Specific for α -1-antitrypsin

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN - 9 1998

Ms. Mary Koning
Regulatory Affairs Specialist
Boehringer Mannheim Corporation
135 Sandberg Street
Thousand Oaks, California 91360

Re: K972640/S1
Trade Name: Tina-quant® α -1-Antitrypsin Assay
Regulatory Class: II
Product Code: DEM
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.

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 Gutman

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): K972640

Device Name: Tina-quant® α -1-antitrypsin Assay

Indications For Use:

Immunological in vitro immunoturbidometric test for the quantitative determination of α -1-antitrypsin in human serum and plasma.

The measurements aid in the diagnosis of several conditions including juvenile and adult cirrhosis of the liver. In addition, alpha-1-antitrypsin deficiency has been associated with pulmonary emphysema.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Peter E Maxim
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K972640