

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
4300 Hacienda Drive
Pleasanton, CA 94588-2722
(925) 730-8413
Fax number: (925) 225-0654

Contact Person: Julie A. Smith

Date Prepared: July 13, 1998

2. Device Name Proprietary name: β 2-microglobulin Control Set Serum
Common name: Controls
Classification name: Single (specified) analyte controls (assayed + unassayed)

3. Predicate device The Boehringer Mannheim β 2-microglobulin Control Set Serum is a new product.
The Boehringer Mannheim β 2-microglobulin Control Set Serum is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the β 2-microglobulin controls contained in the Abbott Imx β 2-microglobulin assay (K890421).

4. Device Description The Boehringer Mannheim β 2-microglobulin Control Set Serum is manufactured using human serum albumin, β 2-microglobulin, and stabilizers. The analyte is appropriately spiked into the control matrix to the correct control concentration levels. The controls are in process checked, and a value assignment process is done via a comparison to an analyte specific (and chemistry specific) calibrator.

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5. Intended use Boehringer Mannheim β 2-microglobulin Control Set Serum is used for the quality control of the Boehringer Mannheim Tinaquant β 2-microglobulin assay.

6. Comparison to predicate device The Boehringer Mannheim β 2-microglobulin Control Set Serum is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the β 2-microglobulin controls contained in the Abbott Imx β 2-microglobulin assay (K890421).

The following table compares the Boehringer Mannheim β 2-microglobulin Controls Set Serum with Abbott β 2-microglobulin controls. Specific data on the performance of the controls have been incorporated into the draft labeling in attachment 5. Labeling for the predicate device is provided in attachment 6.

Similarities:

- Similar intended use
- Same analyte

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Differences:

Feature	β 2-microglobulin Control Set Serum	Abbott β 2-microglobulin control
Control levels	2.50 mg/L 5.50 mg/L	0.2 mg/L 0.6 mg/L 2 mg/L
Matrix	Human Serum	Buffer with protein stabilizers
Preparation	Lyophilized calibrators requiring reconstitution with distilled water.	Ready to use liquid calibrators

6.
Comparison
to predicate
device, (cont.)

Performance Characteristics:

- Dose assignment and stability
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 6 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Julie A. Smith
Boehringer Mannheim Corporation
4300 Hacienda Drive
P.O. Box 9002
Pleasanton, California 94566-0900

Re: K982471
β2-microglobulin Control Set
Regulatory Class: I
Product Code: JJX
Dated: July 13, 1998
Received: July 16, 1998

Dear Ms. Smith:

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 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.

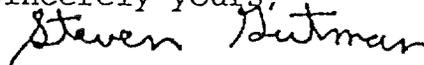
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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~~ K982471

Device Name: β2-microglobulin Control Set Serum

Indications For Use:

The β2-microglobulin Control Set Serum is used for monitoring accuracy and precision of the Boehringer Mannheim Tinaquant β2-microglobulin assay.

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

510(k) Number K982471