

K973358

OCT - 6 1997

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
Concord, CA 94524-4117
(510) 674-0690 extension 8413
Fax number: (510) 687-1850

Contact Person: Yvette Lloyd

Date Prepared: September 30, 1997

2. Device Name

Proprietary name: Myoglobin Control Set

Common name: Controls

Classification name: Single (specified) analyte controls (assayed + unassayed)

3. Predicate device

The Boehringer Mannheim Myoglobin Control Set is a new product.

The Boehringer Mannheim Myoglobin Control Set is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the myoglobin controls contained in the Behring N Latex Myoglobin assay (K902154).

4. Device Description

The Boehringer Mannheim Myoglobin Controls are manufactured using human serum albumin, Myoglobin, 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.

Continued on next page

510(k) Summary, Continued

**5.
Intended use**

The Boehringer Mannheim Myoglobin Controls are used for the quality control of the Boehringer Mannheim Tinaquant Myoglobin assay.

**6.
Comparison
to predicate
device**

The Boehringer Mannheim Myoglobin Control Set is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the myoglobin controls contained in the Behring N Latex Myoglobin assay (K902154).

The following table compares the Boehringer Mannheim Myoglobin Control Set with the predicate device, the Behring Myoglobin Control. Specific data on the performance of the controls have been incorporated into the draft labeling in attachment 5. Labeling for the predicate devices are provided in attachment 6..

Similarities:

- Similar intended use
- Similar matrix

Continued on next page



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT - 6 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K973358
Myoglobin Control Set
Regulatory Class: I
Product Code: JJX
Dated: September 4, 1997
Received: September 8, 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 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.

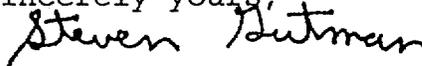
Page 2

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

K973358

Device Name: Myoglobin Control Set

Indications For Use:

The Myoglobin Control Set are used for monitoring accuracy and precision of the Boehringer Mannheim Tinaquant Myoglobin 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)

(Div: _____)

Div: _____

510(k) _____


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