K972433

BOEHRINGER MANNHEIM CORPORATION

Summary

JUL 24 1997

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: June 27, 1997

2. Device name

Proprietary name: CEDIA Digoxin Calibrators

Common name: Therapeutic drug monitoring calibrators for use in the calibration of the CEDIA Digoxin II assay.

Classification name: Calibrators, drug mixture

3. Predicate device

The Boehringer Mannheim CEDIA Digoxin Calibrators are substantially equivalent to the CEDIA Cardiac TDM Multi-Calibrators (K962269).

4. Device Description

The CEDIA Digoxin Calibrators are manufactured using bovine serum albumin, digoxin, stabilizers, and preservatives. The drug is appropriately spiked into the calibrator matrix to the correct calibrator concentration levels. The calibrators are in process checked and quality controlled against in-house reference calibrators (prepared using a similar procedure) which have been value assigned by comparison to the predicate device to ensure correct assay calibration.

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5. Intended use

The CEDIA Digoxin Calibrators are used to calibrate the CEDIA Digoxin II assay on the Beckman Synchron.

6. Comparison to predicate device

The Boehringer Mannheim CEDIA Digoxin Calibrators are substantially equivalent to the CEDIA Cardiac TDM Multi-Calibrators.

The following table compares the CEDIA Digoxin Calibrators with the predicate device, CEDIA Cardiac TDM Multi-Calibrators. Specific data on the performance of the test have been incorporated into the draft labeling in attachment 5. Labeling for the predicate device in provided in attachment 6.

Similarities:

- Similar concentration of digoxin.
- Similar matrix

Differences:

Feature	CEDIA Digoxin Calibrators	CEDIA Cardiac TDM Multi-Cals
Configuration	sold with reagents in kit	sold separately from reagents

Continued on next page

6. Comparison to predicate device, (cont.)

Performance Characteristics:

• Method Comparison: equivalent correlation between predicate device Multi-Calibrators and the CEDIA Digoxin Calibrators.

• Stability: equivalent open vial and shelf-life stability performance to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 24 1997

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

Re: K972433
CEDIA Digoxin Calibrators
Regulatory Class: II
Product Code: DLJ
Dated: June 26, 1997
Received: June 30, 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 (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): N/A

Device Name: CEDIA® Digoxin Calibrators.

Indications For Use:

The CEDIA Digoxin Calibrators are used to calibrate the CEDIA Digoxin II assay on the Synchron.

The CEDIA Digoxin Calibrators are used to determine drug concentrations.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974433