K980853

APR 21 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
4300 Hacienda Drive
Pleasanton, CA 94588-2722
(510) 730-8240
Fax: (510) 225-0654

Contact Person: Betsy Soares-Maddox

Date Prepared: March 2, 1998

2) Device name

Proprietary name: CEDIA® DAU Multi-Drug Calibrators

Common name: Drug of Abuse calibrators for use in the calibration of CEDIA® DAU Assays

Classification name: Calibrators, Drug Mixture

3) Predicate device

We claim substantial equivalence to the Methadone Metabolite Urine Calibrators manufactured by Diagnostic Reagents, Inc.

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510(k) Summary, Continued

4) Device Description

The CEDIA® DAU Multi-Drug Calibrators are manufactured using drug free human urine, various drugs of abuse and a preservative. At this time, the drugs of abuse are d-methamphetamine, secobarbital, nitrazepam, morphine, benzoylecgonine, phencyclidine, and EDDP. The drug raw materials are obtained from a commercially available source and are spiked appropriately into the calibrator matrix to obtain 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 had values confirmed using GC/MS by 3 laboratories.

5) Intended use

The CEDIA® DAU Multi-Drug Calibrators are used for the calibration of qualitative and semiquantitative CEDIA® DAU assays in human urine on automated clinical chemistry analyzers.

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6) Comparison to predicate device

The Boehringer Mannheim Modified CEDIA® DAU Multi-Drug Calibrators are substantially equivalent to other products in commercial distribution intended for similar use. Most notably, the Modified CEDIA® DAU Multi-Drug Calibrators with the addition of EDDP are substantially equivalent to the Methadone Metabolite Urine Calibrators manufactured by Diagnostic Reagents Inc. (DRI).

Feature	DRI EDDP Urine Calibrators	Modified CEDIA® DAU Multi-Drug Calibrators
Matrix	Human Urine	Human Urine
Preservative	Sodium Azide	Sodium Azide
Storage conditions	2-8 ° C	2-8 ° C
Ease of use	Ready to use	Ready to use
EDDP concentration: Cutoff calibrator Intermediate Calibrator High Calibrator	 300 ng/ml 1000 ng/ml 2000 ng/ml	 100 ng/ml 500 ng/ml 2000 ng/ml
Calibrator composition	Single analyte	Multiple analytes
Intended Use	For in vitro diagnostic use for the calibration of enzyme immunoassay for detection of methadone metabolites in human urine.	For use as calibrators in the CEDIA DAU qualitative and semiquantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers.

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6) Comparison to predicate device, (cont.)

Performance Characteristics:

The CEDIA® DAU Multi-Drug Calibrators were analyzed for EDDP by GC/MS in 2 separate laboratories. The results of the study were as follows:

Calibrator	Target [EDDP] ng/mL	Mean [EDDP] ng/mL
Primary Cutoffs	100	103.1
Secondary Cutoffs	100	101.0
Intermediate	500	496.3
High	2000	2033

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 21 1998

Betsy Soares-Maddox
Manager, Regulatory Affairs and Quality Assurance
Boehringer Mannheim Coporation
4300 Hacienda Drive
P.O. Box 9002
Pleasanton, California 94566-0900

Re: K980853
CEDIA® DAU Multi-Drug Calibrators
Regulatory Class: II
Product Code: DKB
Dated: March 2, 1998
Received: March 5, 1998

Dear Ms. Soares-Maddox:

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.

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® DAU Multi-Drug Calibrators

Indications For Use:

The CEDIA® DAU Multi-Drug Calibrators are intended for the calibration of qualitative and semiquantitative CEDIA® DAU Assays on automated clinical chemistry analyzers.

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)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K980853