K980746

MAY 26 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: February 24, 1998

2) Device name

Proprietary name: CEDIA® DAU EDDP Assay

Common name: Homogeneous enzyme immunoassay for the determination of EDDP levels in urine.

Classification name: Methadone test system

3) Predicate device

We claim substantial equivalence to the Methadone Metabolite Enzyme Immunoassay (K931780) manufactured by Diagnostic Reagents, Inc.

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510(k) Summary, Continued

4) Device Description

The CEDIA® DAU EDDP assay uses recombinant DNA technology (US Patent No. 4708929) to produce a unique homogeneous enzyme immunoassay system.

This assay is based on the bacterial enzyme ß-galactosidase, which has been genetically engineered into two inactive fragments. These fragments spontaneously reassociate to form fully active enzyme that, in the assay format, cleaves a substrate, generating a color change that can be measured spectrophotometrically.

In the assay, drug in the sample competes with drug conjugated to one inactive fragment of ß-galactosidase for antibody binding site. If drug is present in the sample, it binds to antibody, leaving the inactive enzyme fragments free to form active enzyme. If drug is not present in the sample, antibody binds to drug conjugated on the inactive fragment, inhibiting the reassociation of inactive ß-galactosidase fragments, and no active enzyme is formed. The amount of active enzyme formed and resultant absorbance change are proportional to the amount of drug present in the sample.

5) Intended use

The CEDIA® DAU EDDP Assay is a homogeneous enzyme immunoassay for the qualitative and semi-quantitative determination of EDDP in human urine on automated clinical chemistry analyzers. Measurements are used as an aid in the diagnosis and treatment of methadone use or overdose.

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510(k) Summary, Continued

6) Comparison to predicate device

The Boehringer Mannheim CEDIA® DAU EDDP Assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Methadone Metabolite Enzyme Immunoassay (K931780) manufactured by Diagnostic Reagents, Inc (DRI).

The following table compares the CEDIA® DAU EDDP Assay with the predicate device, Methadone Metabolite Enzyme Immunoassay.
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:

- Both assays are for the qualitative and semi-quantitative determination of EDDP levels in human urine.
- Both assays utilize a monoclonal antibody.
- Both are enzyme immunoassays.
- Both assays may be used on the same instrumentation.
- Both assays have a similar assay range.

Differences:

- The two assays have different cutoff concentrations.

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510(k) Summary, Continued

6) Comparison to predicate device, (cont.) **Performance Characteristics:**

Feature	DRI Methadone Metabolite EIA			CEDIA® DAU EDDP		
Precision	Intra assay			Intra assay		
Concentration Level	Negative	300 ng/ml	2000 ng/ml	75 ng/ml	100 ng/ml	125 ng/ml
N	10	10	10	21	21	21
%CV	0.1	0.1	0.3	1.1	1.0	1.3
Qualitative Sensitivity	75 ng/mL (2 S.D.)			6.3 ng/mL (3 S.D.)		
Rate Separation						
Negative Calibrator or Low Control to Cutoff	18 mAU/min (0-300 ng/mL)			19.4 mAU/min (75-100 ng/mL)		
Cutoff to High Calibrator or Control	81 mAU/min (300-2000 ng/mL)			13.2 mAU/min (100-125 ng/mL)		
Accuracy	300 ng/mL Cutoff:			100 ng/mL Cutoff:		
				vs. DRI EIA	vs. HPLC	
Relative Sensitivity	Not reported			81.6%	95.4%	
Relative Specificity	Not reported			95.1%	98.2%	
Specificity	Concentration which gives a positive result (ng/mL)			Conc. (ng/mL)	[EDDP] Obs. ng/ml	% Cross-reactivity
EDDP	300			100	100	100
EMDP	400			200000	7.4	0.004
Methadone	5000			600000	98.6	0.016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 26 1998

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

Re: K980746
CEDIA® EDDP® Assay
Regulatory Class: II
Product Code: DJR
Dated: April 24, 1998
Received: April 28, 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.

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 EDDP Assay

Indications For Use:

The CEDIA® DAU EDDP Assay is a homogeneous enzyme immunoassay for the in vitro qualitative and semiquantitative determination of EDDP in human urine on automated clinical chemistry analyzers. Measurements are used as an aid in the diagnosis and treatment of methadone use or overdose.

_____ _____ _____ _____ _____ _____

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 k980746