

K972963

**BOEHRINGER
MANNHEIM
CORPORATION**

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
(510) 674-0667
Fax: (510) 687-1850

Contact Person: Yvette Lloyd

Date Prepared: August 8, 1997

2) Device name Proprietary name: CEDIA DAU PCP Assay

Common name: Homonogeneous enzyme immunoassay for the determination of PCP levels in urine.

Classification name: PCP test system

3) Predicate device We claim substantial equivalence to the CEDIA DAU PCP Assay (K935650).__

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**4) Device
Description**

The CEDIA DAU PCP 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 β -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 β -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 β -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 Modified CEDIA DAU Phencyclidine Assay is a homogeneous enzyme immunoassay for the qualitative and semi-quantitative assay of phencyclidine in human urine. Measurements are used as an aid in the diagnosis and treatment of phencyclidine use or overdose.

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6)
**Comparison
to predicate
device**

The Boehringer Mannheim modified CEDIA DAU PCP Assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Boehringer Mannheim CEDIA DAU PCP Assay (K935650).

The following table compares the modified CEDIA DAU PCP Assay with the predicate device, CEDIA DAU PCP Assay. Specific data on the performance of the test have been incorporated into the draft labeling in attachment 5. Labeling for the predicate device is provided in attachment 6.

Similarities:

- Both assays are for qualitative and semiquantitative determination of PCPs in urine.
- Same chemistry parameters

Differences:

- The modified CEDIA DAU PCP assay uses a different antibody and ED-conjugate
- The modified CEDIA DAU PCP assay has lower crossreactivity to diphenhydramine.

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

Feature	Modified CEDIA DAU PCP	CEDIA DAU PCP
Precision	Modified NCCLS (mA/min): 25 ng/mL Cutoff Protocol	Modified NCCLS (mA/min): 25 ng/mL Cutoff Protocol
Concentration		
Level	19 25 31	19 25 31
N	126 126 126	120 120 120
Within-Run	281.1 323.1 370.4	238.4 276.4 316.3
%CV	0.7 0.7 0.6	1.0 1.2 1.1
Total	281.1 323.1 370.4	238.4 276.4 316.3
%CV	1.5 1.5 1.4	4.3 5.3 5.0
Qualitative Sensitivity 25ng/mL Cutoff	1.05 ng/ml	1.7 ng/ml
Semiquantitative Sensitivity 25ng/mL Cutoff	0.96 ng/ml	N/A
Accuracy	Vs. CEDIA PCP Assay	Vs. Commercially available EIA Assay
25 ng/mL Cutoff Sensitivity	96.9%	99.1
Specificity	100.0%	100.0%

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**Comparison
to predicate
device (cont.)**

Feature	Modified CEDIA DAU PCP	CEDIA DAU PCP
Interfering substances	Less than 10% error at:	Less than 10% error at:
Acetone	1 g/dL	1 g/dL
Ascorbic Acid	1.5 g/dL	1.5 g/dL
Creatinine	0.5 g/dL	0.5 g/dL
Ethanol	1 g/dL	1 g/dL
Galactose	10 mg/dL	10 mg/dL
γ-globulin	0.5 g/dL	0.5 g/dL
Glucose	3 g/dL	3 g/dL
Hemoglobin	0.3 g/dL	0.3 g/dL
Human Serum		
Albumin	0.5 g/L	0.5 g/L
Oxalic Acid	0.1g/dL	0.1g/dL
Riboflavin	7.5 mg/dL	7.5 mg/dL
Sodium Chloride	6 g/dL	6 g/dL
Urea	5 g/dL	3 g/dL
Specificity	Multiple PCP compounds	Multiple PCP compounds



SEP 22 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: K972963
CEDIA DAU PCP Assay
Regulatory Class: II
Product Code: LCM
Dated: August 8, 1997
Received: August 11, 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.

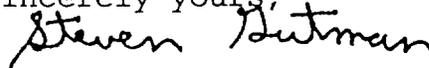
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice 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 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 PCP Assay

Indications For Use:

The modified CEDIA® DAU PCP Assay is a homogeneous enzyme immunoassay for the in vitro qualitative and semiquantitative assay of PCPs in human urine. Measurements are used as an aid in the diagnosis and treatment of PCP use or overdose.

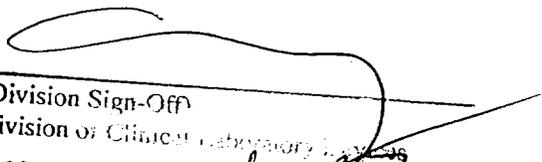
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Clinical Laboratory _____
510(k) Number AKA 2963