DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 30, 2017

Dade Behring Inc.
Ms. Judy McInnis-Berger
Senior Regulatory Specialist
Route 896, Glasgow Business Center
P.O. Box 6101
Newark, Delaware 19714

Re: k000462
Trade/Device Name: Urine Phencyclidine (PCP) Screen Flex reagent cartridge
Regulation Number: Unclassified
Regulation Name: Enzyme Immunoassay, Phencyclidine
Regulatory Class: Unclassified, 510(k) required
Product Code: LCM
Dated: February 9, 2000
Received: February 11, 2000

Dear Ms. McInnis-Berger:

This letter corrects our substantially equivalent letter of April 6, 2000.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and
Radiological Health

Enclosure

Device Name: Urine Phencyclidine (PCP) Screen Flex® reagent cartridge

Indications for Use:

The PCP Flex® reagent cartridge used on the Dimension® clinical chemistry system provides reagents for an *in vitro* diagnostic test intended for the qualitative and semi-quantative determination of phencyclidine in human urine. Measurements obtained with the PCP method are used in the diagnosis and treatment of phencyclidine use or overdose.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K004672

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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)

APR 6 2000

K000462

DADE BEHRING

DADE BEHRING INC.
P.O. Box 6101
Newark, DE 19714

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. Manufacturer and Contact Information:

Manufacturer – Final Product	Dade Behring Inc. Chemistry Group Route 896 Newark, DE 19702
Contact Information	Judy McInnis-Berger or Cathy P. Craft Dade Behring Inc. GBC Bldg 500 Mailbox 514 P.O. Box 6101 Newark, DE 19714-6101
Manufacturer – Bulk Product	Syva Company - Dade Behring Inc. 20400 Mariani Ave. Cupertino, CA 95014

2. Device Classification Name:

"Phencyclidine test system" has been classified as Class II by the Clinical Chemistry and Clinical Toxicology Devices Panel. Reference: Federal Register, Volume 52, Number 84, May 1987

3. Intended Use:

The PCP Flex® reagent cartridge used on the Dimension® clinical chemistry system provides reagents for an *in vitro* diagnostic test intended for the qualitative and semi-quantative determination of phencyclidine in human urine. Measurements obtained with the PCP method are used in the diagnosis and treatment of phencyclidine use or overdose.

4. Device Description and Characteristics:

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

The Urine Phencyclidine (PCP) Screen Flex® reagent cartridge is a homogenous enzyme assay intended for use in qualitative and semiquantitative analysis of phencyclidine in human urine. The PCP method has been found to be substantially equivalent to the predicate device, Abbott AxSYM® System Phencyclidine II Assay, with regard to intended use, assay sample, and overall performance characteristics.

Comparative Analysis

The Dimension® method showed excellent correlation to the Abbott AxSYM® System Phencyclidine II Assay (comparative method) in qualitative analysis. 213 specimens were tested. 42 samples were positive and 166 amples were negative by both methods. The percent agreement between the PCP method and the comparative method using the 25 ng/mL cutoff result was 98%. Five (5) discordant sample was positive by the PCP method and negative by the AxSYM® method. The GC/MS values are listed below:

Discrepant specimens (ng/mL):

GC/MS (Phencyclidine)
24
20
25
19
44

All positive samples and a portion of negative samples (n=42), as assessed by the PCP method, were analyzed by GC/MS for confirmatory purposes. The comparative analyses demonstrated a good relationship between the semiquantitative analyses and GC/MS values.

Spiked Sample Recovery

The qualitative and semiquantitative attributes were assessed by determining the accuracy of recovery for the analyte in spiked samples PCP method.

For the qualitative method, known levels of phencyclidine, spiked at levels less than or equal to minus 25% of the 25 ng/mL cutoff (0 – 18.75) and spiked levels greater than or equal to plus 25% of the 25ng/mL cutoff (31.25 – 1000 ng/mL) were consistently distinguished as negative or positive.

The semiquantitative results for known spiked concentrations for the Urine Phencyclidine (PCP) Screen Flex® reagent cartridge quantitated within 10% of the nominal concentration between 8 and 75 ng/mL.

Precision

A precision study was performed on the 25 ng/mL cutoff level and controls at +/- 25% of the cutoff using the Dimension® PCP method in the semiquantitative mode. Acceptable within run and total precision statistics in the semiquantitative assay were observed.

In the semiquantitative mode the with-in run precision demonstrated coefficients of variation (%CV) for controls and cutoff concentrations ranging from 2.1 to 5.0% and for total precision %CV ranging from 5.5 to 6.5%.

5. **Substantial Equivalence:**
   In conclusion, Dade Behring Inc. considers the Urine Phencyclidine (PCP) Screen Flex® reagent cartridge to be substantially equivalent to the Abbott AxSYM® System Phencyclidine II Assay with regard to intended use, assay sample, and overall performance characteristics.