K062162

SEP 14 2006

510(k) Summary for the
Dimension Vista™ System Drugs of Abuse Calibrator
(UDAT CAL – KC510)

A. 510(k) Number:

B. Analytes: Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Methaqualone (MTQ), Opiates (OPI), Phencyclidine (PCP), Propoxyphene (PRX), and Cannabinoids (THC).

C. Type of Test: Calibrator Material

D. Applicant: Dade Behring Inc., P.O. Box 6101, Newark, DE 19714-6101
Victor M. Carrio, Regulatory Affairs and Compliance Manager
Office: (302) 631-0376 Fax: (302) 631-6299

E. Proprietary and Established Names:

Dimension Vista™ System Drugs of Abuse Calibrator
(UDAT CAL – KC510)

F. Regulatory Information:

1. Regulation section: 21 CFR § 862-1150 – Calibrator
2. Classification: Class II
3. Product Code: DKB – Calibrator, Drug Mixture
4. Panel: Toxicology

G. Intended Use: The UDAT CAL is an *in vitro* diagnostic product for the calibration of Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Methaqualone (MTQ), Opiates (OPI), Phencyclidine (PCP), Propoxyphene (PRX), and Cannabinoids (THC) methods on the Dimension Vista™ System.

H. Device Description:

UDAT CAL is a liquid, multi-analyte, drug free human urine based product containing:

Analyte	Constituent
Amphetamine/Methamphetamine	D-methamphetamine
Barbiturate	Secobarbital
Benzodiazepines	Lormetazepam
Cocaine Metabolite	Benzoylecgonine
Methadone	Methadone
Opiates	Morphine
Phencyclidine	Phencyclidine
Cannabinoids	11-nor-Δ^9-THC-9 –COOH
Propoxyphene	Propoxyphene
Methylqualone	Methylqualone

The kit consists of six vials, three vials of Calibrator A, and three vials of Calibrator B which are ready for use (no preparation is required). The volume per vial is 2.5 mL for Calibrator A and 2.6 mL for Calibrator B. Intermediate levels are automatically prepared and corresponding values calculated by the Dimension Vista™ System.

I. Substantial Equivalence Information:

	New Device	**Predicate Device**
Item	**Dimension Vista™ System Drugs of Abuse Calibrator**	**Syva® EMIT® Calibrators/Controls K993755**
Intended Use	The UDAT CAL is an *in vitro* diagnostic product for the calibration of Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Methaqualone (MTQ), Opiates (OPI), Phencyclidine (PCP), Propoxyphene (PRX), and Cannabinoids (THC) methods on the Dimension Vista™ System.	The Emit® Calibrators/Controls are used in the calibration of the Emit® II Plus Amphetamines, Barbiturate, Benzodiazepine, Cannabinoid, Cocaine Metabolite, Ecstasy, Methadone, Methaqualone, Monoclonal Amphetamine/Methamphetamine, Opiates, Phencyclidine, and Propoxyphene Assays.
Analytes	Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Methaqualone (MTQ), Opiates (OPI), Phencyclidine (PCP), Propoxyphene (PRX), and Cannabinoids (THC).	Amphetamines, Barbiturate, Benzodiazepine, Cannabinoid, Cocaine Metabolite, Ecstasy, Methadone, Methaqualone, Monoclonal Amphetamine/Methamphetamine, Opiates, Phencyclidine, and Propoxyphene.
Form	Liquid.	Liquid.
Traceability	USP[1] for all analytes except: BENZ – Benzodiazepine (99% purity) (Cerilliant)[2]. COC – Cocaine (99% purity) (Cerilliant). THC – Cannabinoids (99% purity) (Cerilliant).	USP for all analytes except: BENZ – Benzodiazepine (99% purity) (Cerilliant). COC – Cocaine (99% purity) (Cerilliant). THC – Cannabinoids (99% purity) (Cerilliant).Standards.
Matrix	Human urine based.	Human urine based.
Number of Levels	Two levels[3].	Six levels.

[1] United States Pharmacopeia.

[2] Cerilliant Inc. 811 Paloma Drive, Suite A Roundrock, TX 78664
[3] Intermediate levels are automatically prepared and corresponding values calculated by the Dimension Vista™ System.

J. Standard/Guidance Document Referenced:

1. Guidance: Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final, 02/22/1999
Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use, 11/30/2004

2. Standards: CEN 13640 Stability testing of In-Vitro Diagnostic Devices
ISO 14971:2000 Medical devices -Application of risk management to medical devices

K. Performance Characteristics:

1. Stability: Target shelf life for the Dimension Vista™ System Drugs of Abuse Calibrator is nine months. Calibrator shelf life is determined by comparing results of the product stored at 4°C with control stored at -20°C. The method is calibrated from this stored material. The 4°C material values are recovered versus the calibration. Recovery versus time is monitored and percent change over time is determined. Percent change should be less than or equal to 10%. Shelf-life stability (expiration) dating assignment at commercialization reflects the real-time data on file at Dade Behring, Inc.
A vial punctured by the instrument and stored on board is stable for 24 hours.
An open vial not on instrument, but recapped and stored in a refrigerator is stable for 31 days.

   For testing, vials are opened /punctured on day zero. For punctured vials, a quantity of calibrator sufficient for multiple calibrations is removed and the vials are recapped, punctured and stored at 2-8°C. Punctured vials are tested on Day 0, 1, 2, and 8 vs. freshly opened vials. For manually opened vials, half of the volume is removed and vials are recapped and tested on day 32 vs. freshly opened vials.

2. Traceability: The assigned values of the UDAT CAL are traceable to:

Analyte	Constituent	Reference Material
Amphetamine / Methamphetamine	D-methamphetamine	USP[1] 1429000; USP 1399001
Barbiturate	Secobarbital	USP 1611004

Benzodiazepines	Lormetazepam	Benzodiazepine (99% purity) (Cerilliant)[2]
Cocaine Metabolite	Benzoylecgonine	Cocaine (99% purity) (Cerilliant)
Methadone	Methadone	USP 1398009
Opiates	Morphine	USP 1448005
Phencyclidine	Phencyclidine	USP 1516003
Cannabinoids	11-nor-Δ^9-THC-9 – COOH	Cannabinoids (99% purity) (Cerilliant)
Propoxyphene	Propoxyphene	USP 1404000
Methylqualone	Methylqualone	USP 1575000

[1] United States Pharmacopeia.
[2] Cerilliant Inc. 811 Paloma Drive, Suite A Roundrock, TX 78664

3. Bottle Value Assignment:

D-Methamphetamine, Secobarbital, Lormetazepam, Benzoylecgonine, Methadone, Morphine, Phencyclidine, 11-nor-Δ^9-THC-9-COOH, Propoxyphene, and Methylqualone Reference Material is weighed into drug free normal human urine at five levels and stored at -70° C.
The verification of the Master Lot values are compared against previously approved Master Lot values and GC/MS[1] testing. The approved Master Lot values were assigned with an instrument calibrated with the corresponding standard reference material.

The stock solution is made by adding D-Methamphetamine, Secobarbital, Lormetazepam, Benzoylecgonine, Methadone, Morphine, Phencyclidine, 11-nor-Δ^9-THC-9-COOH, Propoxyphene, and Methylqualone Reference Materials gravimetrically to stock solution at target concentrations and verified on an instrument calibrated with a previously approved Master Lot.

The commercial lot is made by adding calculated quantities of stock solution to drug free normal human urine in appropriate concentrations for each of the calibrator levels. The concentration of each level is verified using an instrument calibrated with Master Lot and GC/MS testing of each analyte in the Commercial lot. Values for each analyte are approved once the acceptable ranges for each analyte are met. The commercial lot is then filled, capped, labeled, and packaged.

[1] Gas Chromatography / Mass Spectrometry.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 14 2006

Mr. Victor Carrio
Dade Behring, Inc.
P.O. Box 6101
Newark, DE 19714

Re: K062162
Trade/Device Name: Dimension Vista™ System Drugs of Abuse Calibrator (UDAT CAL – KC510)
Regulation Number: 21 CFR 862.3200
Regulation Name: Clinical toxicology calibrator
Regulatory Class: Class II
Product Code: DKB
Dated: July 27, 2006
Received: July 28, 2006

Dear Mr. Carrio:

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.

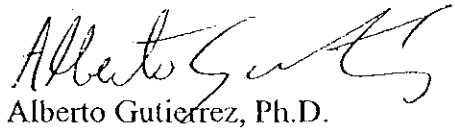
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K062162

Device Name:

Dimension Vista™ System Drugs of Abuse Calibrator
(UDAT CAL – KC510)

Indications for Use:

The UDAT CAL is an *in vitro* diagnostic product for the calibration of Amphetamines /Methamphetamines (AMPH), Barbiturates (BARB), Benzodiazepines (BENZ), Cocaine Metabolite (COC), Methadone (METH), Methaqualone (MTQ), Opiates (OPI), Phencyclidine (PCP), Propoxyphene (PRX), and Cannabinoids (THC) methods on the Dimension Vista™ System.

Prescription Use __X__ **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

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

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K062162