# 510(k) Summary

NOV 2 2 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K062017

1. **Submitter name, address, contact**

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-4041
Contact Person: Marlene Hanna

2. **Preparation Date**

September 25, 2006

3. **Device name**

**Trade or Proprietary Names:**
VITROS Chemistry Products AMPH Reagent
VITROS Chemistry Products Calibrator Kit 26
VITROS Chemistry Products FS Calibrator 1
VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV, and V

**Common Names**:
Amphetamine assay and controls and controls

**Classification Names:**
1. Amphetamine test system (21 CFR 862.3100) Class II
2. Clinical toxicology calibrators (21 CFR 862.3200) Class II
3. Clinical toxicology control material (21 CFR 862.3280) DAT Performance Verifiers I, II ,III, IV, andV) are assayed controls, so they meet the reserved criteria under Section 510(l) of the Food, Drug, and Cosmetic Act.

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**4. Predicate Devices**

The VITROS Chemistry Products AMPH assay is substantially equivalent to the Syva® EMIT II Plus Amphetamines assay.

The VITROS Chemistry Products DAT Performance Verifiers are substantially equivalent to the Bio-Rad Liquicheck™ UrineToxicology Controls.

**5. Device description**

The VITROS AMPH assay is a homogeneous enzyme immunoassay that is performed using the VITROS Chemistry Products AMPH Reagent with the VITROS Chemistry Products Calibrator Kit 26, VITROS Chemistry Products FS Calibrator 1, and VITROS Chemistry Products FS Diluent Pack 4 (DAT Diluent / DAT Diluent 2) on VITROS 5,1 FS Chemistry Systems.

The VITROS AMPH Reagent is a dual chambered package containing ready-to-use liquid reagents that are used to detect amphetamines in urine. Sample, calibrators, and controls are automatically treated with surfactant (DAT Diluent 2) prior to addition of reagents. Treated sample is added to Reagent 1 containing antibodies reactive to d-amphetamine and d-methamphetamine, glucose-6-phosphate and nicotinamide adenine dinucleotide ($NAD^+$), followed by Reagent 2 containing d-amphetamine and d-methamphetamine, both labeled with the enzyme glucose-6-phosphate dehydrogenase (G6P-DH). The assay is based on competition between amphetamines in the treated urine sample and the d-amphetamine and d-methamphetamine labeled with the enzyme glucose-6-phosphate dehydrogenase (G6P-DH) for antibody binding sites. Enzyme activity decreases upon binding to the antibody, therefore the concentration of amphetamines in the urine sample is directly proportional to measured enzyme activity. Active enzyme converts oxidized nicotinamide adenine dinucleotide ($NAD^+$) to NADH, resulting in an absorbance change that is measured spectrophotometrically at 340 nm.

The VITROS Chemistry Products Calibrator Kit 26 is prepared from human urine to which drugs of abuse, metabolites of drugs of abuse, organic salt, surfactants, and preservative have been added. VITROS Chemistry Products FS Calibrator 1 is prepared from sodium chloride and processed water. These standards are used to calibrate VITROS 5,1 FS Chemistry Systems for the qualitative and semi-quantitative measurement of amphetamines (AMPH).

The VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV, and V are quality control materials prepared from a human urine pool to which analytes, surfactant, and preservative have been added. These are assayed controls used to monitor performance of VITROS AMPH assay on VITROS 5,1 FS Chemistry Systems.

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The VITROS Chemistry Products FS Diluent Pack 4 (DAT Diluent / DAT Diluent 2) is a common reagent that is used by multiple assays on the VITROS 5,1 FS Chemistry System. This is a dual chambered package containing two ready-to-use liquid diluents. DAT Diluent is prepared from human urine to which organic salt, surfactants, and preservative have been added. DAT Diluent 2 is prepared from processed water to which surfactant and preservative have been added.

The VITROS 5,1 FS Chemistry System is a clinical chemistry instrument that provides automated use of the VITROS Chemistry Products MicroTip® and MicroSlides® range of products. The VITROS 5,1 FS System was cleared for market by 510(k) premarket notification (K031924).

**6. Device intended uses**

**VITROS Chemistry Products AMPH Reagent**: For *in vitro* diagnostic use only. VITROS Chemistry Products AMPH Reagent is used on VITROS 5,1 FS Chemistry Systems for the semi-quantitative or qualitative determination of amphetamines (AMPH) in human urine using a cutoff of either 500 or 1000 ng/mL. Measurements obtained with the VITROS AMPH method are used in the diagnosis and treatment of amphetamines use or overdose.

The VITROS Chemistry Products AMPH assay is intended for use by professional laboratory personnel. It provides only a preliminary test result. A more specific alternative chemical method must be used to confirm a result obtained with this assay. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when evaluating a preliminary positive result.

**VITROS Chemistry Products Calibrator Kit 26:** For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 26 is used to calibrate VITROS 5,1 FS Chemistry Systems for the qualitative or semi-quantitative measurement of drugs of abuse.

**VITROS Chemistry Products FS Calibrator 1:** For *in vitro* diagnostic use only. VITROS Chemistry Products FS Calibrator 1 is used in conjunction with VITROS Chemistry Products Calibrator Kits to calibrate VITROS 5,1 FS Chemistry Systems

**VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV, and V:** For *in vitro* diagnostic use only. VITROS Chemistry Products DAT Performance Verifiers are assayed controls used to monitor performance of urine drugs of abuse screening assays on VITROS 5,1 FS Chemistry Systems. .

**7. Comparison to predicate devices:**

The VITROS Chemistry Products AMPH assay and VITROS Chemistry Products DAT Performance Verifiers are substantially equivalent to the Syva® EMIT II Plus Amphetamines assay (K031004) and Bio-Rad Liquicheck™ Urine Toxicology Controls (K022707) predicate devices which were cleared by the FDA for IVD use.

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The performance of the VITROS AMPH assay on the VITROS 5,1 FS Chemistry System was compared to the Syva® EMIT II Plus Amphetamines assay on the SYVA 30R System. The results demonstrated good agreement between the two immunoassay methods.

The VITROS AMPH assay and VITROS DAT Controls have the following similarities to the predicate devices: same intended use, the same cutoff values of 500 and 1000 ng/mL, are liquid, ready to use reagents, have similar performance characteristics, are used on an automated clinical chemistry analyzer and calibrated against the same drug, methamphetamine.

**Table 1** Similarities and differences of the assays performed using the VITROS AMPH assay and DAT controls and the Syva EMIT II Plus Amphetamines assay and Bio-Rad Urine Toxicology controls.

| **Device Similarities** | | |
|---|---|---|
| **Device Characteristic** | **Description** | |
| Indications for Use | For *in vitro* diagnostic use only. The assays are intended for use in the qualitative and semi-quantitative analysis of amphetamines in human urine. The controls are assayed controls used to monitor the performance of Chemistry Systems. | |
| Test Principle | Homogeneous enzyme immunoassay | |
| Cut-Off values | 500 or 1000 ng/mL | |
| Specimen Type | Human Urine | |
| Reagent Format | Liquid ready to use | |
| Antibody source | Mouse monoclonal antibodies reactive to d-amphetamine and d-metamphetamine | |
| Calibration traceability | d-metamphetamines with confirmation by GC/MS | |
| Calibrator matrix | Human urine | |
| Control matrix | Human urine | |
| **Device Differences** | | |
| **Device Characteristic** | **VITROS AMPH assay (New device)** | **Emit® Amphetamines assay (Predicate device)** |
| Cut-Off values | 500 or 1000 ng/mL | 300, 500, or 1000 ng/mL |
| Calibrator levels | 6 levels | Qualitative: Two levels<br>Semi-quantitative: 300 ng/mL Cutoff value: Four levels; 500 and 1000 ng/mL cutoff values: Five levels |
| Calibrator format | Frozen Liquid ready to use | Refrigerated liquid ready to use |
| Instrumentation | To be used on VITROS 5,1 FS Chemistry Systems | Multiple automated clinical chemistry systems |
| Controls: Drugs Reported | Cocaine metabolites (benzoylecgonine), benzodiazepines (lormetazepam), methadone, amphetamines (d-methamphetamine), opiates (morphine), cannabinoids (11-nor-delta-THC-9-COOH), phencyclidine and barbiturates (secobarbital). | Methamphetamine, secobarbital, lormetazepam, tetrahydrocannabinol (THC), benzoylecgonine, ethanol, lysergic acid diethylamide (LSD), methadone, methaqualone, morphine, (Free), phencyclid ine, propoxyphene, nortriptyline and addition of creatinine, pH, specific gravity. |
| Controls: Number of Levels | Five | Two |

**8. Conclusions** The data presented in the premarket notification provide a reasonable assurance that the VITROS Chemistry Products AMPH Reagent, VITROS Chemistry Products Calibrator Kit 26, VITROS Chemistry Products FS Calibrator 1, and the VITROS Chemistry Products DAT Performance Verifiers are safe and effective for the stated intended uses and are substantially equivalent to the cleared predicate devices. Equivalence to the predicates was demonstrated using a commercially available assay along with patient samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Marlene Hanna
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Rochester, NY 14626-5101

NOV 2 2 2006

Re: k0602077
Trade/Device Name: VITROS Chemistry Products AMPH Reagent
VITROS Chemistry Products Calibrator Kit 26
VITROS Chemistry Products FS Calibrator 1
VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV, and V
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DLJ, DIF
Dated: September 27, 2006
Received: September 28, 2006

Dear Ms. Hanna:

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Carol Benson for

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



**510(k) Number (if known):** K062077

**Device Name:** VITROS Chemistry Products AMPH Reagent

**Indications for Use:**

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The VITROS Chemistry Products AMPH assay is intended for use by professional laboratory personnel. It provides only a preliminary test result. A more specific alternative chemical method must be used to confirm a result obtained with this assay. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when evaluating a preliminary positive result.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

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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

K062077

## Indications for Use



**510(k) Number (if known):** K062077

**Device Name:** VITROS Chemistry Products Calibrator Kit 26
VITROS Chemistry Products FS Calibrator 1
VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV, and V.

**Indications for Use:**

For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 26 is used to calibrate VITROS 5,1 FS Chemistry Systems for the qualitative or semi-quantitative measurement of drugs of abuse.

For *in vitro* diagnostic use only. VITROS Chemistry Products FS Calibrator 1 is used in conjunction with VITROS Chemistry Products Calibrator Kits to calibrate VITROS 5,1 FS Chemistry Systems.

For *in vitro* diagnostic use only. VITROS Chemistry Products DAT Performance Verifiers are assayed controls used to monitor performance of urine drugs of abuse screening assays on VITROS 5,1 FS Chemistry Systems.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Carol Benson

Division Sign-Off

**Office of In Vitro Diagnostic Device Evaluation and Safety**

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