1.0 510(k) Summary

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: K042520

1.1 Submitter name, address, contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
Phone: (585) 453-3482
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Contact Person: Carey A. Mayo, M.S., RAC

1.2 Date of Preparation: September 15, 2004

1.3 Device Proprietary Name(s)

Trade Name(s) VITROS Chemistry Products CAFFN Reagent Kit
VITROS Chemistry Products TDM Performance Verifier I, II, and III

Common Name Caffeine assay and controls

1.4 Classification Name(s)

Theophylline Test System: Class II (21 CFR 862.3880)
Assayed Controls: Class I, reserved (21 CFR 862.1660)

1.5 Predicate devices

The VITROS Chemistry Products CAFFN assay is substantially equivalent to the SYVA® Emit® Caffeine Assay (Dade Behring, Inc.)

The modified VITROS Chemistry Products TDM Performance Verifiers are substantially equivalent to the VITROS Chemistry Products TDM Performance Verifiers currently in commercial distribution.

1.6 Device description

The VITROS 5,1 FS Chemistry System is a fully automated clinical chemistry analyzer intended for use in the in vitro determination of various analytes in human specimens. The VITROS 5,1 FS Chemistry System is designed for use with VITROS Chemistry Products MicroTip and Thin Film assays.

The system is comprised of four main elements:

1. The VITROS 5,1 FS Chemistry System – instrumentation, which provides automated use of the chemistry reagents. The VITROS 5,1 FS Chemistry System was cleared for market by a separate 510(k) premarket notification (K031924).

2. The VITROS Chemistry Products range of MicroTip assays, in this case the VITROS Chemistry Products CAFFN Reagent Kit (Reagents 1 and 2, Buffer and Calibrators) and the VITROS Chemistry Products TDM Performance Verifiers, which are combined by the VITROS 5,1 FS Chemistry System to perform the VITROS CAFFN assay.

3. The VITROS Chemistry Products Thin Film range of products, which are dry, multilayered, analytical elements, coated on polyester supports. The thin film products each have their own 510(k) clearance numbers and were cleared for market for use on the VITROS 5,1 FS Chemistry System through submission of information required by the ODE Guidance Document: "Data For Commercialization Of Original Equipment Manufacturer, Secondary and Generic Reagents For Automated Analyzers". The required information was provided in the VITROS 5,1 FS Chemistry System premarket notification (K031924).

4. Common reagents used by multiple assays on the VITROS System (in this case, VITROS Chemistry Products FS Diluent Pack 3).

The VITROS System and reagents are designed specifically for use with the VITROS Chemistry Products range of products.

1.7 Device intended use

VITROS Chemistry Products CAFFN Reagent Kit: For *in vitro* diagnostic use only. VITROS Chemistry Products CAFFN Reagent Kit is used on the VITROS 5,1 FS Chemistry System to quantitatively measure caffeine (CAFFN) concentration in human serum and plasma of subjects undergoing therapy with caffeine, especially for cases of neonatal apnea.

VITROS Chemistry Products TDM Performance Verifier I, II and III: For *in vitro* diagnostic use only. VITROS TDM Performance Verifier is an assayed control used to monitor performance of ACET, CRBM, DGXN, PHBR, PHYT and CAFFN on VITROS Chemistry Systems.

1.8 Comparison to predicate device: Reagent Kit

The VITROS Chemistry Products CAFFN Reagent Kit is substantially equivalent to the SYVA Emit Caffeine Assay, which was cleared by FDA (K853872) for IVD use. For this device, the intended use includes the application of the test in monitoring patients treated with caffeine as a therapeutic agent for neonatal apnea [1,2]. Treatment of neonatal apnea with caffeine was approved by the FDA (9/21/99, NDA #020793).

The relationship between the VITROS CAFFN assay and the predicate device, determined by least squares linear regression, is:

VITROS CAFFN assay = 0.9995 X – 0.04 μg/mL
with a correlation coefficient of 0.989, where X is the predicate device.

In addition to the above mentioned correlation study, studies were performed to determine the precision, expected values, linearity, and specificity of the VITROS CAFFN assay, (refer to the VITROS Chemistry Products CAFFN Reagent Kit Instructions for Use for summaries of the results of these studies).

The table below lists the characteristics of the VITROS Chemistry Products CAFFN Assay and the predicate device.

Device Characteristic	VITROS Chemistry Products CAFFN Assay (New device #1)	SYVA Emit Caffeine Assay (Predicate device #1)
Intended Use	Quantitative measurement of caffeine concentration in human serum and plasma of subjects undergoing therapy with caffeine, especially for cases of neonatal apnea.	Quantitative measurement of caffeine as a metabolite.
Basic principle	Homogeneous enzyme immunoassay	Homogeneous enzyme immunoassay
Reportable Range	1 – 30 µg/mL	1 – 30 µg/mL
Instrumentation	VITROS 5,1 FS Chemistry System	SYVA-30R Biochemical System
Sample type	Serum and plasma	Serum

1.9 Comparison to predicate device: Performance Verifiers

The modified VITROS Chemistry Products TDM Performance Verifiers are identical in intended use, base matrix, storage and handling and instructions for use as the previously cleared VITROS Chemistry Products TDM Performance Verifiers currently in commercial distribution (K984288). The only difference is the addition of caffeine to the controls. The labeling will be updated to add assigned values for caffeine so that the TDM Performance Verifiers may be used with the VITROS Chemistry Products CAFFN assay.

1.10 Conclusions

The data presented in the premarket notification provide a reasonable assurance that the VITROS Chemistry Products CAFFN assay and the VITROS TDM 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

NOV 3 0 2004

Ms. Carey A. Mayo, MS., RAC
Regulatory Affairs Associate
Ortho-Clinical Diagnostics
100 Indigo Creek Drive
Rochester, NY 14626-5101

Re: k042520
Trade/Device Name: VITROS Chemistry Products CAFFN Reagent Kit
VITROS Chemistry Products TDM Performance Verifiers, I, II, and III
Regulation Number: 21 CFR 862.3880
Regulation Name: Theophylline test system
Regulatory Class: Class II
Product Code: KLS, DIF
Dated: November 12, 2004
Received: November15, 2004

Dear Ms. Mayo:

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,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting 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): K042520

Device Name:

1. VITROS Chemistry Products CAFFN Reagent Kit
2. VITROS Chemistry Products TDM Performance Verifiers I, II, and III

Indications For Use:

1. For *in vitro* diagnostic use only. VITROS Chemistry Products CAFFN Reagent Kit is used on the VITROS 5,1 FS Chemistry System to quantitatively measure caffeine (CAFFN) concentration in human serum and plasma of subjects undergoing therapy with caffeine, especially for cases of neonatal apnea.
2. For *in vitro* diagnostic use only. VITROS TDM Performance Verifier is an assayed control used to monitor performance of ACET, CRBM, DGXN, PHBR, PHYT and CAFFN on VITROS Chemistry Systems.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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) K042520