

OCT 28 2004

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3.0 510(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: K042006

3.1 Submitter name, address, contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
Phone: (585) 453-4253
Fax: (585) 453-3368

Contact Person: Darlene J. Phillips

3.2 Date of Preparation:

July 23, 2004

3.3 Device Proprietary Names:

Trade Names	VITROS Chemistry Products dHDL Slides VITROS Chemistry Products Calibrator Kit 25 VITROS Chemistry Products Performance Verifiers I and II
Common Name	HDL Cholesterol assay

3.4 Classification Names

Classification Name: Lipoprotein test system (862.1475): Class I: The Clinical Chemistry and Toxicology Panel of the FDA has placed lipoprotein test systems in Class I. Since this device is an *in vitro* device intended for use in assessing the risk of cardiovascular diseases, it meets the reserved criteria under Section 510(l) of the Food, Drug, and Cosmetic Act.

Classification Name: Calibrator (862.1150): Class II The Clinical Chemistry and Toxicology Panel of the FDA has placed calibrators in Class II.

Classification Name: Quality Control material (assayed and unassayed) (862.1660): Class I: The Clinical Chemistry and Toxicology Panel of the FDA has placed Quality Control material (assayed and unassayed) for clinical chemistry in Class I. Since this device is an assayed control, it meets the reserved criteria under Section 510(l) of the Food, Drug, and Cosmetic Act.

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3.5 Predicate device

3.5.1 The VITROS Chemistry Products dHDL Slides and VITROS Chemistry Products Calibrator Kit 25 are substantially equivalent to the Automated HDL Cholesterol (AHDL) Flex® reagent cartridge for use with the Dade Behring Dimension® analyzer.

3.5.2 The VITROS Chemistry Products Performance Verifiers I and II are substantially equivalent to the VITROS Chemistry Products Performance Verifiers I and II.

3.6 Device description

The VITROS Chemistry Systems are fully automated clinical chemistry analyzers intended for use in the *in vitro* determination of various analytes in human specimens (serum, plasma, urine, and cerebrospinal fluid).

The system is comprised of four main elements:

1. The VITROS Chemistry System - instrumentation, which provides automated use of the chemistry reagents. The VITROS Chemistry Systems were cleared for market by separate premarket notifications:

VITROS 250/250AT Chemistry Systems (K922072 cleared July 10, 1992)

VITROS 950/950AT Chemistry Systems (K946090 cleared January 17, 1995)

VITROS 5,1 FS Chemistry System (K031924 cleared August 7, 2003)

2. The VITROS Chemistry Products MicroSlides™ range of products, in this case the VITROS Chemistry Products dHDL Slides, VITROS Chemistry Products Calibrator Kit 25 and VITROS Chemistry Products Performance Verifier I and II which are combined by the VITROS Chemistry Systems to perform the VITROS dHDL Slide assay.

3. The VITROS Chemistry Products MicroTip™ range of liquid reagent products that are formulated for use only on the VITROS 5,1 FS Chemistry System. The VITROS Chemistry Products dHDL Reagent and VITROS Chemistry Products Calibrator Kit 19 were cleared for market by premarket notification K031924, August 7, 2003; further VITROS MicroTip assays will be submitted under separate 510(k) submissions, as required.

4. Common reagents used by multiple assays on the VITROS Chemistry Systems, in this case VITROS Chemistry Products 7% BSA (K903071 cleared September 27, 1990).

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

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3.7 Device intended use

3.7.1 VITROS Chemistry Products dHDL Slides

For *in vitro* diagnostic use only. VITROS Chemistry Products dHDL Slides are used to quantitatively measure HDL cholesterol (HDLC) concentration in serum and plasma. High Density Lipoprotein (HDL) cholesterol is used to evaluate the risk of developing coronary heart disease (CHD). The risk of CHD increases with lower HDL cholesterol concentrations.

3.7.2 VITROS Chemistry Products Calibrator Kit 25

For *in vitro* diagnostic use. VITROS Chemistry Products Calibrator Kit 25 is used to calibrate VITROS Chemistry Systems for the quantitative measurement of HDL cholesterol using VITROS Chemistry Products dHDL Slides.

3.7.3 VITROS Chemistry Products Performance Verifiers I and II

For *in vitro* diagnostic use only. The VITROS Chemistry Products Performance Verifiers I and II are assayed controls used to monitor performance on VITROS Chemistry Systems.

3.8 Comparison to predicate device

3.8.1 The VITROS Chemistry Products dHDL Slide and VITROS Chemistry Products Calibrator Kit 25 are substantially equivalent to the AHDL Flex reagent cartridge assay on the Dimension system (predicate device) which was cleared by the FDA (K032798) for IVD use.

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

VITROS dHDL Slides assay = $0.953 \times X - 0.64$ mg/dL,

with a correlation coefficient of 0.996,

where X is the AHDL Cholesterol assay on the Dade Dimension clinical chemistry analyzer.

In addition to the above mentioned correlation study, studies were performed to determine the precision, analytical sensitivity, specificity and expected values of the VITROS dHDL Slides assay, (refer to VITROS dHDL Slides Instructions For Use for summaries of the results of these studies).

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Table 1 Table 1 lists the characteristics of the VITROS dHDL Slides assay (new device) and the AHDL Cholesterol assay (predicate device).

Device Characteristic	VITROS dHDL Slide assay (New Device)	Dimension AHDL assay (Predicate Device)
Reportable Range	5.0 - 110.0 mg/dL	0 – 150 mg/dL
Specimen Pretreatment	None Required: Homogeneous direct assay	None Required: Homogeneous direct assay
Basic principle	Precipitation and partitioning of non-HDL lipoproteins, followed by detergent solubilization of HDL followed by enzyme-coupled colorimetric quantitation of residual cholesterol in HDL fraction, in a self-contained solid state reagent carrier	Polyanion complexing of non-HDL lipoproteins, accompanied by detergent solubilization of HDL followed by enzyme-coupled colorimetric quantitation of residual cholesterol in HDL fraction
Reagents	Dry chemistry, ready to use	Liquid reagents, ready to use
Test Type	Colorimetric endpoint	Bichromatic endpoint
Instrumentation	VITROS Chemistry Systems	Dade Dimension clinical chemistry systems
Sample type	Serum, heparin plasma, and EDTA plasma	Serum and plasma
Sample volume	10 µL	3 µL
Reaction steps	Step 1: Precipitation of non-HDL lipoproteins Step 2: Detergent solubilization of HDL Step 3: Measurement	Step 1: Polyanion complexing of non-HDL lipoproteins Step 2: Detergent solubilization of HDL Step 3: Measurement
Incubation Temperature	37°C	37°C

3.8.2 The VITROS Chemistry Products Performance Verifiers I and II are substantially equivalent to the VITROS Chemistry Products Performance Verifiers (predicate device) which were cleared by the FDA (K904768) for IVD use.

Table 2 Table 2 lists the similarities and differences of the device characteristics between the VITROS Performance Verifiers with the predicate device, VITROS Performance Verifiers I and II.

Device Characteristic	New device	Predicate device
Intended Use	VITROS Performance Verifier is an assayed control used to monitor performance on VITROS Chemistry Systems. (New additional intended use: to monitor performance of VITROS dHDL Slides assay on the VITROS Chemistry Systems.)	VITROS Performance Verifier is an assayed control used to monitor performance on VITROS Chemistry Systems.
Matrix of Performance Verifiers	A base matrix of freeze-dried human serum to which enzymes, electrolytes, stabilizers, preservatives and other organic analytes have been added.	A base matrix of freeze-dried human serum to which enzymes, electrolytes, stabilizers, preservatives and other organic analytes have been added.
Performance Verifier Levels	Low and High	Low and High

3.9 Conclusions

The data presented in the premarket notification provide a reasonable assurance that the VITROS dHDL Slides assay and the VITROS Chemistry Products Performance Verifiers are safe and effective for the stated intended uses and are substantially equivalent to the cleared predicate devices. The data in this premarket notification demonstrate that the performance of the VITROS dHDL Slides assay and Performance Verifiers are substantially equivalent to the cleared predicate devices.

Equivalence to the predicates was demonstrated using commercially available reagents along with patient samples.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 28 2004

Ms. Darlene J. Phillips
Regulatory Associate
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626

Re: k042006
Trade/Device Name: VITROS Chemistry Products dHDL Slides
VITROS Chemistry Products Calibrators Kit 25
VITROS Chemistry Products Performance Verifiers I and II
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I
Product Code: LBS, JIS, JJY
Dated: October 4, 2004
Received: October 5, 2004

Dear Ms. Phillips:

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.

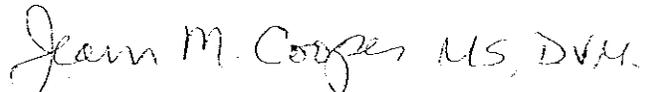
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

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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,



Jean M. Cooper, MS, D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

1.0 Indications for Use

510(k) Number (if known): K042006

Device Name: VITROS Chemistry Products dHDL Slides
VITROS Chemistry Products Calibrator Kit 25
VITROS Chemistry Products Performance Verifiers I and II

Indications for Use: For *in vitro* diagnostic use only. VITROS dHDL Slides are used to quantitatively measure HDL cholesterol (HDLC) concentration in serum and plasma. High Density Lipoprotein (HDL) cholesterol is used to evaluate the risk of developing coronary heart disease (CHD). The risk of CHD increases with lower HDL cholesterol concentrations.

For *in vitro* diagnostic use. VITROS Chemistry Products Calibrator Kit 25 is used to calibrate VITROS Chemistry Systems for the quantitative measurement of HDL cholesterol using VITROS Chemistry Products dHDL Slides.

For *in vitro* diagnostic use only. VITROS Chemistry Products Performance Verifiers I and II are assayed controls used to monitor performance on VITROS Chemistry Systems.

Prescription Use 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 Device Evaluation (ODE)


Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042006