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Chapter 1 – Summary Information

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: K04 1720

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

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

Contact Person: Marlene A. Hanna

2. **Preparation date**

Date 510(k) prepared: June 23, 2004

3. **Device name**

Trade or Proprietary Name:
VITROS Chemistry Products dLDL Reagent
VITROS Chemistry Products Calibrator Kit 19
VITROS Chemistry Products FS Calibrator 1
VITROS Chemistry Products Performance Verifiers I and II

Common Name: Direct LDL assay

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: 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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4. **Predicate Device**

a. The VITROS Chemistry Products dLDL assay is substantially equivalent to the Polymedco Lipi+Plus Direct LDL assay.

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

5. **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 (serum, plasma, urine, and cerebrospinal fluid). The VITROS 5,1 FS 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 MicroTip range of liquid reagent products (in this case VITROS Chemistry Products dLDL Reagent, VITROS Chemistry Products Calibrator Kit 19 and VITROS Chemistry Products FS Calibrator 1, VITROS Chemistry Products Performance Verifiers I and II), which are combined by the VITROS 5,1 FS Chemistry System to perform the VITROS dLDL assay.

3. The VITROS Chemistry Products Thin Film range of dry products, which are dry, multilayered, analytical elements, coated on polyester supports. The thin film products each have there 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 2 and VITROS Chemistry Products FS Reconstitution Diluent).

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

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6. **Device intended use**

a. VITROS Chemistry Products dLDL Reagent: For *in vitro* diagnostic use only. The VITROS Chemistry Products dLDL Reagent is used to quantitatively measure LDL Cholesterol (LDLC) concentration in serum and plasma. Low Density Lipoprotein (LDL) cholesterol is used to evaluate the risk of developing coronary heart disease (CHD). The risk of CHD increases with higher LDL cholesterol concentration.

b. VITROS Chemistry Products Calibrator Kit 19 and VITROS Chemistry Products FS Calibrator 1: For *in vitro* diagnostic use only. The VITROS Chemistry Products Calibrator Kit 19 is used in conjunction with VITROS FS Calibrator 1 to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of HDL and LDL cholesterol using VITROS dHDL and dLDL Reagents.

c. 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.

7. **Comparison to predicate device(s):**

Reagent Pack and Calibrators
The VITROS Chemistry Products dLDL Reagent and VITROS Chemistry Products Calibrator Kit 19 and FS Calibrator 1 are substantially equivalent to the Polymedco Lipi+Plus Direct LDL assay (predicate device) which was cleared by the FDA (K020852) for IVD use.

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

VITROS dLDL = 1.031 x X – 3.81 (mg/dL),
with a correlation coefficient of 0.9908,
where X is the Polymedco Lipi+Plus Direct LDL assay on a Dade Dimension clinical chemistry analyzer.

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

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Table 1 lists the characteristics of the assays performed using the VITROS dLDL assay and the Polymedco Lipi+Plus Direct LDL assay.

Table 1

Table 1 lists the characteristics of the VITROS dLDL (new device) and the dLDL (predicate device).

Device Characteristic	VITROS dLDL (New device)	dLDL (Predicate device)
Reportable Range	30 – 350 mg/ dL	0 – 1000 mg/dL
Specimen Pretreatment	None Required: Homogeneous assay	None Required: Homogeneous assay
Basic Principle	Elimination enzymatic test	Elimination enzymatic test
Reagents	Liquid ready to use	Liquid ready to use
Instrumentation	VITROS 5,1 FS Chemistry System	Dade Dimension clinical chemistry system
Sample Type	Serum and Plasma (heparin)	Serum and Plasma (heparin and EDTA)
Reaction steps	Step 1: Elimination Step 2: Measurement	Step 1: Elimination Step 2: Measurement
Incubation Temperature	37 °C	37 °C

Performance Verifiers

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	VITROS dLDL (New device)	dLDL (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 LDL Cholesterol on the VITROS 5,1 FS Chemistry System.)	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

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Conclusions

The data presented in the premarket notification provide a reasonable assurance that the VITROS dLDL 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 dLDL assay and Performance Verifiers are substantially equivalent to the cleared predicate device(s).

Equivalence to predicate(s) was demonstrated using commercially available reagents along with patient samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
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AUG 2 5 2004

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

Re: k041720
Trade/Device Name: VIRTOS Chemistry Products dLDL Reagent
VIRTOS Chemistry Products Calibrator Kit 19
VIRTOS Chemistry Products FS Calibrator 1
VIRTOS Chemistry Products Performance Verifiers I and II
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT, JJX, MRR,
Dated: June 23, 2004
Received: June 24, 2004

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,

Jean M. Cooper MS, DVM.

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

Indications for Use

510(k) Number (if known): K041720

Device Name(s): VITROS Chemistry Products dLDL Reagent
VITROS Chemistry Products Calibrator Kit 19
VITROS Chemistry Products FS Calibrator 1
VITROS Chemistry Products Performance Verifiers I and II

Indications for Use: For *in vitro* diagnostic use only. VITROS Chemistry Products dLDL Reagent is used to quantitatively measure LDL Cholesterol (LDLC) concentration in serum and plasma. Low Density Lipoprotein (LDL) cholesterol is used to evaluate the risk of developing coronary heart disease (CHD). The risk of CHD increases with higher LDL cholesterol concentrations.

For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 19 is used in conjunction with VITROS FS Calibrator 1 to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of HDL and LDL cholesterol using VITROS dHDL and dLDL Reagents.

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 _____
(Per 21 CFR 801 Subpart D) (Per 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)

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Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K041720