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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: K042521

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: September 15, 2004

3. Device name

Trade or Proprietary Name(s):
VITROS Chemistry Products ApoA1 Reagent
VITROS Chemistry Products Calibrator Kit 21
VITROS Chemistry Products ApoA1 Performance Verifier I

VITROS Chemistry Products ApoB Reagent
VITROS Chemistry Products Calibrator Kit 22
VITROS Chemistry Products ApoB Performance Verifier I

Common Name(s):
Apolipoprotein A1 (ApoA1) assay
Apolipoprotein B (ApoB) assay

Classification Name(s):
Lipoprotein test systems (862.1475): Class: I (general controls). Since these devices (ApoA1 and ApoB reagent) are used in assessing risk of artherosclerosis, they meet the reserved criteria under Section 510(l) of the Food, Drug, and Cosmetic Act.

Calibrator (862.1150): Calibrator Kits 21 and 22: Class II.

Quality Control material (assayed and unassayed) (862.1660): Class I (general controls). Since these devices (ApoA1 and ApoB Performance Verifiers I) are assayed controls, they meet the reserved criteria under Section 510(l) of the Food, Drug, and Cosmetic Act.

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4. Predicate Devices

a. The VITROS Chemistry Products ApoA1 assay is substantially equivalent to the Dade Behring N Antisera to Human Apolipoprotein A-1 Reagent and N Apoliprotein Standard Serum.
b. The VITROS Chemistry Products ApoB assay is substantially equivalent to the Dade Behring N Antisera to Human Apolipoprotein B Reagent and N Apoliprotein Standard Serum.
c. The VITROS Chemistry Products ApoA1 and ApoB Performance Verifiers I are substantially equivalent to the Dade Behring Apolipoprotein Control Serum CHD.

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 ApoA1 Reagent and VITROS Chemistry Products Calibrator Kit 21, VITROS Chemistry Products ApoB Reagent and VITROS Chemistry Products Calibrator Kit 22, VITROS Chemistry Products ApoA1 Performance Verifier I and VITROS Chemistry Products ApoB Performance Verifier I), which are combined by the VITROS 5,1 FS Chemistry System to perform the VITROS ApoA1 and ApoB assays.

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 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 1).

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

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6. **Device(s) intended use**

a. VITROS Chemistry Products ApoA1 Reagent: For *in vitro* diagnostic use only. VITROS Chemistry Products ApoA1 Reagent is used to quantitatively measure apolipoprotein A1 (ApoA1) concentration in human serum and plasma.

b. VITROS Chemistry Products ApoB Reagent: For *in vitro* diagnostic use only. VITROS Chemistry Products ApoB Reagent is used to quantitatively measure apolipoprotein B (ApoB) concentration in human serum and plasma.

c. VITROS Chemistry Products Calibrator Kit 21: For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 21 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of apolipoprotein A1 (ApoA1).

d. VITROS Chemistry Products Calibrator Kit 22: For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 22 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of apolipoprotein B (ApoB).

e. **VITROS Chemistry Products ApoA1 Performance Verifier I:** For *in vitro* diagnostic use only. VITROS Chemistry Products ApoA1 Performance Verifier I is an assayed control used to monitor the performance of ApoA1 Reagent on VITROS 5,1 FS Chemistry Systems.

f. **VITROS Chemistry Products ApoB Performance Verifier I:** For *in vitro* diagnostic use only. VITROS Chemistry Products ApoB Performance Verifier I is an assayed control used to monitor the performance of ApoB Reagent on VITROS 5,1 FS Chemistry Systems.

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

Apo A1 Reagent Pack and Calibrators
The VITROS Chemistry Products ApoA1 Reagent and VITROS Chemistry Products Calibrator Kit 21 are substantially equivalent to the Dade Behring N Antisera to Human Apolipoprotein A-1 Reagent (K860894) and N Apoliprotein Standard Serum (K041870) (predicate devices) which were cleared by the FDA for IVD use.

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The relationship between the VITROS ApoA1 and the predicate device, determined by least squares linear regression, is:

$$\text{VITROS ApoA1} = 0.98\ X - 13.04\ (\text{mg/dL}),$$

with a correlation coefficient of 0.987,
where X is Dade Behring N Antisera to Human Apolipoprotein A-1 Reagent assay.

Apo B Reagent Pack and Calibrators
The VITROS Chemistry Products ApoB Reagent and VITROS Chemistry Products Calibrator Kit 22 are substantially equivalent to the Dade Behring N Antisera to Human Apolipoprotein B Reagent (K860894) and N Apoliprotein Standard Serum (K041870) (predicate devices) which were cleared by the FDA for IVD use.

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

$$\text{VITROS ApoB} = 1.00\ X - 3.88\ (\text{mg/dL}),$$

with a correlation coefficient of 0.985,
where X is Dade Behring N Antisera to Human Apolipoprotein B Reagent assay.

In addition to the above mentioned correlation study, studies were performed to determine the precision, specificity, linearity, antigen excess, lower limit of detection, and expected values of the VITROS ApoA1 and ApoB assays, (refer to the VITROS ApoA1 and ApoB Reagent's 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 ApoA1 andApoB assays and the Dade Behring N Antisera to Human Apolipoprotein A-1 Reagent and the Dade Behring N Antisera to Human Apolipoprotein B Reagent assays.

Table 1

Table 1 lists the characteristics of the VITROS ApoA1 and ApoB (new devices) and the DADE Apo A-1 and Apo B (predicate device).

Device Characteristic	**VITROS ApoA1 and ApoB (New device)**	**DADE Apo A-1 and ApoB (Predicate device)**
Intended Use	For *in vitro* diagnostic use only. VITROS Chemistry Products ApoA1 and ApoB Reagents are used to quantitatively measure apolipoprotein A1 (ApoA1) and apolipoprotein B (ApoB) concentration in human serum and plasma.	*In vitro* diagnostic reagents for the quantitative determination of apolipoprotein A-1 (Apo A-1) and apolipoprotein B (Apo B) in human serum.
Method	Immunoturbidimetric	Immunoturbidimetric
Reportable Range: ApoA1: ApoB:	 30.00 – 240.00 mg/dL 35.00 – 300.00 mg/dL	 19 – 600 mg/dL 25 – 400 mg/dL
Sample Type	Human Serum	Human Serum
Reactive Ingredients ApoA1: ApoB:	 Goat antisera to human apolipoprotein A1 Goat antisera to human apolipoprotein B	 Rabbit antisera to Human ApoA-1 Rabbit antisera to Human ApoB
Instrumentation	VITROS 5,1 FS Chemistry System	DADE BN ProSpec

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Performance Verifiers

The VITROS Chemistry Products ApoA1 and ApoB Performance Verifiers I are substantially equivalent to the Dade Behring Apolipoprotein Control Serum CHD (predicate device) which was cleared by the FDA (K993310) for IVD use.

Table 2 lists the similarities and differences of the device characteristics between the VITROS ApoA1 and ApoB Performance Verifiers I with the predicate device, the Dade Behring Apolipoprotein Control Serum CHD.

Table 2

Device Characteristic	VITROS ApoA1 and ApoB (New Device)	DADE ApoA1 andApoB (Predicate Device)
Intended Use	For *in vitro* diagnostic use only. VITROS Chemistry Products ApoA1 and ApoB Performance Verifiers I are assayed controls used to monitor the performance of ApoA1 and ApoB Reagent on VITROS 5,1 FS Chemistry Systems.	Apolipoprotein Control Serum CHD is used as an assayed control for accuracy and precision in the quantitative immunochemical determination of apolipoprotein A-1 and B with the Behring Nephelometer Systems.
Matrix	Prepared from processed human serum to which inorganic salts, buffers, organic compounds, bovine serum albumin, and preservatives have been added.	Stabilized reagent from human serum.
Form	Liquid	Lyophilized
Volume	0.5 mL per vial	0.5 mL per vial

Conclusions The data presented in the premarket notification provide a reasonable assurance that the VITROS ApoA1 and ApoB assays and the VITROS Chemistry Products ApoA1 and ApoB Performance Verifiers are safe and effective for the stated intended uses and are substantially equivalent to the cleared predicate devices.

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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Ms. Marlene A Hanna, RAC
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NOV 18 2004

Re: k042521
Trade/Device Name: VITROS Chemistry Products ApoA1 Reagent
VITROS Chemistry Products Calibrator Kit 21
VITROS Chemistry Products ApoA1 Performance Verifier I
VITROS Chemistry Products ApoB Reagent
VITROS Chemistry Products Calibrator Kit 22
VITROS Chemistry Products ApoB Performance Verifier I
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT, MSJ, JJX
Dated: September 15, 2004
Received: September 16, 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,

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 for the ApoA1 assay

510(k) Number (if known):

Device Name(s): VITROS Chemistry Products ApoA1 Reagent
VITROS Chemistry Products Calibrator Kit 21
VITROS Chemistry Products ApoA1 Performance Verifier I

Indications for Use:

For *in vitro* diagnostic use only. VITROS Chemistry Products ApoA1 Reagent is used to quantitatively measure apolipoprotein A1 (ApoA1) concentration in human serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 21 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of apolipoprotein A1 (ApoA1).

For *in vitro* diagnostic use only. VITROS Chemistry Products ApoA1 Performance Verifier I is an assayed controls used to monitor the performance of ApoA1 Reagent on VITROS 5,1 FS Chemistry Systems.

Prescription Use ✓ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042521

Indications for Use for the ApoB assay

510(k) Number (if known):

Device Name(s):

VITROS Chemistry Products ApoB Reagent
VITROS Chemistry Products Calibrator Kit 22
VITROS Chemistry Products ApoB Performance Verifier I

Indications for Use:

For *in vitro* diagnostic use only. VITROS Chemistry Products ApoB Reagent is used to quantitatively measure apolipoprotein B (ApoB) concentration in human serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 22 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of apolipoprotein B (ApoB).

For *in vitro* diagnostic use only. VITROS Chemistry Products ApoB Performance Verifier I is an assayed controls used to monitor the performance of ApoB Reagent on VITROS 5,1 FS Chemistry Systems.

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

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Device Evaluation and Safety

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