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: **K063144**.

Submitter Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive MC00881
Rochester, New York 14626-5101

Contact Person: Sarah Parsons
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Preparation date October 13, 2006

Trade or Proprietary Name:
VITROS Chemistry Products dHDL Reagent Pack
VITROS Chemistry Products Calibrator Kit 19
VITROS Chemistry Products FS Calibrator 1
VITROS® 5,1 FS Chemistry System / enGen™ Laboratory Automation System

Common Name: HDL Cholesterol assay
Clinical Chemistry Analyzer / Laboratory Automation System

Classification Name: Lipoprotein test system: 21 CFR 862.1475
Calibrator: 21 CFR 862.1150
Discrete photometric chemistry analyzer for clinical use: 21 CFR 862.2160

Device Intended Use: The VITROS Chemistry Products dHDL assay is intended for the *in vitro* quantitative measurement of HDL cholesterol in human serum or plasma.

The VITROS 5,1 FS Chemistry System with enGen™ Laboratory Automation System is intended for use in the *in vitro* quantitative measurement of a variety of analytes of clinical interest, using both VITROS Chemistry Products Slides (colorimetric endpoint, rate, ion-selective electrode, and immunorate methods) and VITROS Chemistry Products MicroTip liquid reagents (spectrophotometric and spectrophotometric immunoassay methods.)

Device description: The modified device is the VITROS Chemistry Products dHDL Reagent Pack, VITROS Chemistry Products Calibrator Kit 19 and VITROS Chemistry Products FS Calibrator 1 which are combined by the VITROS 5,1 FS Chemistry System with enGen Laboratory Automation System to perform the VITROS dHDL assay for HDL cholesterol. The VITROS HDL assay has not been changed.

The VITROS 5,1 FS Chemistry System (instrumentation, which provides automated use of chemistry reagents) is interfaced to a Laboratory Automation System, which conducts pre-analytical and post-analytical sample and data management.

Substantial Equivalence The modified device has the same intended use, fundamental scientific technology and operating principle as the predicate device. The VITROS dHDL assay performed on the VITROS® 5,1 FS Chemistry System with enGen™ Laboratory Automation System is substantially equivalent to the VITROS dHDL assay performed on the VITROS® 5,1 FS Chemistry System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Sarah Parsons
Manager, Regulatory Affairs
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101

NOV 13 2006

Re: k063144
Trade/Device Name: VITROS Chemistry Products dHDL Reagent Pack
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I
Product Code: LBR, JIT, JJE
Dated: October 13, 2006
Received: October 16, 2006

Dear Ms. Parsons:

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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

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: Instrument with Automation and Assay.

510(k) Number (if known): K063144

Device Name: VITROS 5,1 FS Chemistry System with enGen™ Laboratory Automation System
VITROS Chemistry Products dHDL Reagent Pack
VITROS Chemistry Products Calibrator Kit 19
VITROS Chemistry Products FS Calibrator 1

Indications for Use: The VITROS 5,1 FS Chemistry System with enGen™ Laboratory Automation System is intended for use in the *in vitro* quantitative measurement of a variety of analytes of clinical interest, using both VITROS Chemistry Products Slides (colorimetric endpoint, rate, ion-selective electrode, and immunorate methods) and VITROS Chemistry Products MicroTip liquid reagents (spectrophotometric and spectrophotometric immunoassay methods.)

The VITROS Chemistry Products dHDL Reagent Pack, VITROS Chemistry Products Calibrator Kit 19 and VITROS Chemistry Products FS Calibrator 1 are used for the quantitative measurement of HDL cholesterol in serum or plasma.

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)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division [illegible]

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K063144