510(k) Summary

OCT 23 2008

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: K081543

Submitter:

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

Contact Person:

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Preparation date:

September 22, 2008

Registration Number:

The establishment number for the VITROS Immunodiagnostic Products TSH Reagent Pack and Calibrators is 9680658.

The establishment number for the VITROS Chemistry Products PHYT Slides is 1319809.

The establishment number for the VITROS Chemistry Products Calibrator Kit 9 is 1319808.

The establishment number for the VITROS 5600 Integrated System is 1319681.

Purpose for Submission:

Ortho-Clinical Diagnostics hereby submits this Special 510(k) to provide notification of modification to the VITROS Immunodiagnostic Products TSH assay and VITROS Chemistry Products PHYT assay. The TSH assay is cleared for use with the VITROS ECi/ECiQ Immunodiagnostic System. The PHYT assay is cleared for use with the VITROS 5,1 FS Chemistry System. The modifications include the use of the VITROS TSH and PHYT assays with the VITROS 5600 Integrated System. The VITROS 5600 Integrated System is a new member of the VITROS family of analyzers and uses reagents, calibrators and controls identical to the VITROS ECi/ECiQ Immunodiagnostic System and VITROS 5,1 FS Chemistry System. The VITROS 5600 Integrated System is an integration of the VITROS 5,1 FS Chemistry System, which performs MicroSlide and MicroTip assays and the VITROS ECi/ECiQ Immunodiagnostic System, which performs MicroWell assays. The VITROS 5,1 FS Chemistry System was cleared as part of Premarket Notification number K031924. The VITROS ECi/ECiQ Immunodiagnostic System was cleared as part of Premarket Notification number K962919.

Trade or Proprietary Name:	VITROS® Immunodiagnostic Products TSH Reagent Pack VITROS® Immunodiagnostic Products TSH Calibrators VITROS® Chemistry Products PHYT Slides VITROS® Chemistry Products Calibrator Kit 9 VITROS® 5600 Integrated System
Common Name:	VITROS TSH Test System, VITROS PHYT Test System
Classification Name:	Thyroid Stimulating Hormone Test System (21 CFR 862.1690); Diphenylhydantoin test system (21 CFR 862.3350); Calibrators (21 CFR 862.1150); Discrete photometric chemistry analyzer for clinical use (21 CFR 862.2160); Fluorometer for clinical use (21 CFR 862.2560)
Device Intended Use:	VITROS Immunodiagnostic Products TSH Reagent Pack For the *in vitro* quantitative measurement of thyroid stimulating hormone (TSH) in human serum and plasma (EDTA or Heparin) using the VITROS ECi/ECiQ Immunodiagnostic Systems and VITROS 5600 Integrated System to aid in the differential diagnosis of thyroid disease. VITROS Immunodiagnostic Products TSH Calibrators For *in vitro* use in the calibration of the VITROS ECi/ECiQ Immunodiagnostic Systems and VITROS 5600 Integrated System for the quantitative measurement of thyroid stimulating hormone (TSH) in human serum and plasma (EDTA or Heparin). VITROS Chemistry Products PHYT Slides For *in vitro* diagnostic use only. VITROS Chemistry Products PHYT Slides quantitatively measure phenytoin (PHYT) concentration in serum and plasma usingVITROS 250/350/950 and 5,1 FS Chemistry Systems and the VITROS 5600 Integrated System. VITROS Chemistry Products Calibrator Kit 9 For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 9 is used to calibrate VITROS 250/350/950 and 5,1 FS Chemistry Systems and the VITROS 5600 Integrated System for the quantitative measurement of ACET, CRBM, DGXN, PHBR, and PHYT. VITROS 5600 Integrated System For use in the *in vitro* quantitative, semi-quantitative, and qualitative measurement of a variety of analytes of clinical interest, using VITROS Chemistry Products Slides, VITROS Chemistry Products MicroTip Reagents and VITROS Immunodiagnostic Products Reagents.

Device description:

The VITROS Immunodiagnostic Products TSH assay and VITROS Chemistry Products PHYT assay are intended for use on the VITROS 5600 Integrated System.

The VITROS 5600 Integrated System combines the existing VITROS 5,1 FS Chemistry System (K031924) and the VITROS ECi/ECiQ Immunodiagnostic System (K962919) into a single system. All technology, methodologies and analytical methods currently available on the existing two systems are available on the new integrated system.

Substantial Equivalence:

The modified devices have the same intended use, fundamental scientific technology and operating principle as the predicate devices. The VITROS Immunodiagnostic Products TSH Assay is substantially equivalent to the product previously cleared with Premarket Notification number K964558. The VITROS Chemistry Products PHYT Assay is substantially equivalent to the product previously cleared with Premarket Notification number K941142.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Leah Van De Water, M.S., RAC
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100 Indigo Creek Drive
MC881
Rochester, NY 14626-5101

OCT 23 2008

Re: k081543
Trade/Device Name: VITROS Immunodiagnostic Products TSH Reagent Pack
VITROS Immunodiagnostic Products TSH Calibrators
VITROS Chemistry Products PHYT Slides
VITROS Chemistry Products Calibrator Kit 9
VITROS 5600 Integrated System
Regulation Number: 21 CFR 862.1690
Regulation Name: Thyroid Stimulating Hormone test system
Regulatory Class: Class II
Product Code: JLW, DIP, JJE, JIT
Dated: September 24, 2008
Received: September 25, 2008

Dear Ms. Van De Water:

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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., 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

510(k) Number (if known):

Device Name: VITROS Immunodiagnostic Products TSH Reagent Pack
VITROS Immunodiagnostic Products TSH Calibrators
VITROS Chemistry Products PHYT Slides
VITROS Chemistry Products Calibrator Kit 9
VITROS 5600 Integrated System

Indications for Use:

VITROS Immunodiagnostic Products TSH Reagent Pack

For the *in vitro* quantitative measurement of thyroid stimulating hormone (TSH) in human serum and plasma (EDTA or Heparin) using the VITROS ECi/ECiQ Immunodiagnostic Systems and VITROS 5600 Integrated System to aid in the differential diagnosis of thyroid disease.

VITROS Immunodiagnostic Products TSH Calibrators

For *in vitro* use in the calibration of the VITROS ECi/ECiQ Immunodiagnostic Systems and VITROS 5600 Integrated System for the quantitative measurement of thyroid stimulating hormone (TSH) in human serum and plasma (EDTA or Heparin).

VITROS Chemistry Products PHYT Slides

For *in vitro* diagnostic use only. VITROS Chemistry Products PHYT Slides quantitatively measure phenytoin (PHYT) concentration in serum and plasma using VITROS 250/350/950 and 5,1 FS Chemistry Systems and the VITROS 5600 Integrated System.

VITROS Chemistry Products Calibrator Kit 9

For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 9 is used to calibrate VITROS 250/350/950 and 5,1 FS Chemistry Systems and the VITROS 5600 Integrated System for the quantitative measurement of ACET, CRBM, DGXN, PHBR, and PHYT.

VITROS 5600 Integrated System

For use in the *in vitro* quantitative, semi-quantitative, and qualitative measurement of a variety of analytes of clinical interest, using VITROS Chemistry Products Slides, VITROS Chemistry Products MicroTip Reagents and VITROS Immunodiagnostic Products Reagents.

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

...on Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K 081543