DEC 22 2008

6 510(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: K083173.

Submitter:

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

Contact Person:

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Preparation date:

October 24, 2008

Registration Number:

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

The establishment number for the VITROS 3600 Immunodiagnostic 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 Reagent Pack and VITROS Immunodiagnostic Products TSH Calibrators. The reagent pack and calibrators were previously cleared for use with the VITROS ECi/ECiQ Immunodiagnostic System and VITROS 5600 Integrated System (K081543). The modifications include the use of the VITROS TSH Reagent Pack and Calibrators with the VITROS 3600 Immunodiagnostic System.

The VITROS 3600 Immunodiagnostic System is a new member of the VITROS family of analyzers and uses VITROS Immunodiagnostic reagents, calibrators and controls identical to the VITROS ECi/ECiQ Immunodiagnostic System and VITROS 5600 Integrated System. The VITROS 3600 Immunodiagnostic System uses the existing VITROS ECi/ECiQ Immunodiagnostic System technology and adds increased operating efficiency and throughput by utilizing the same immunoassay hardware and software subsystem design as the VITROS 5600 Integrated System. The VITROS ECi/ECiQ Immunodiagnostic System was cleared as part of Premarket Notification number K962919. The VITROS 5600 Integrated System was cleared as part of Premarket Notification number K081543.

Trade or Proprietary Name:	VITROS® Immunodiagnostic Products TSH Reagent Pack VITROS® Immunodiagnostic Products TSH Calibrators VITROS® 3600 Immunodiagnostic System
Common Name:	VITROS TSH Test System
Classification Name:	Thyroid Stimulating Hormone Test System (21 CFR 862.1690); Calibrators (21 CFR 862.1150); 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, VITROS 3600 Immunodiagnostic System 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, VITROS 3600 Immunodiagnostic System and VITROS 5600 Integrated System for the quantitative measurement of thyroid stimulating hormone (TSH) in human serum and plasma (EDTA or Heparin). VITROS 3600 Immunodiagnostic System For use in the *in vitro* quantitative, semi-quantitative, and qualitative measurement of a variety of analytes of clinical interest, using VITROS Immunodiagnostic Products Reagents.
Device description:	The VITROS Immunodiagnostic Product TSH Reagent and Calibrators is intended for use on the VITROS 3600 Immunodiagnostic System. The VITROS 3600 Immunodiagnostic System utilizes the existing VITROS ECi/ECiQ Immunodiagnostic System technology (K962919) and adds increased operating efficiency and throughput by utilizing the same immunoassay hardware and software subsystem design as the VITROS 5600 Integrated System (K081543). All VITROS Immunodiagnostic Product technology, methodologies and analytical methods currently available on the existing two systems (VITROS ECi/ECiQ Immunodiagnostic System and VITROS 5600 Integrated System) are available on the new VITROS 3600 Immunodiagnostic System.
Substantial Equivalence:	The modified device has the same intended use, fundamental scientific technology and operating principle as the predicate device. The modified VITROS Immunodiagnostic Products

TSH assay is substantially equivalent to the product previously cleared with Premarket Notification number K081543.

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
Regulatory Affairs Associate
Ortho-Clinical Diagnostics
100 Indigo Creek Drive
MC881
Rochester, NY 14626-5101

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Re: k083173
Trade/Device Name: VITROS Immunodiagnostic Products TSH Reagent Pack
VITROS Immunodiagnostic Products TSH Calibrators
VITROS 3600 Immunodiagnostic System
Regulation Number: 21 CFR 862.1690
Regulation Name: Thyroid Stimulating Hormone test system
Regulatory Class: Class II
Product Code: JLW, JJE, JIT
Dated: December 15, 2008
Received: December 16, 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

2 Indications for Use

510(k) Number (if known): K083173

Device Name:

VITROS Immunodiagnostic Products TSH Reagent Pack
VITROS Immunodiagnostic Products TSH Calibrators
VITROS 3600 Immunodiagnostic 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, VITROS 3600 Immunodiagnostic System 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, VITROS 3600 Immunodiagnostic System and VITROS 5600 Integrated System for the quantitative measurement of thyroid stimulating hormone (TSH) in human serum and plasma (EDTA or Heparin).

VITROS 3600 Immunodiagnostic System
For use in the *in vitro* quantitative, semi-quantitative, and qualitative measurement of a variety of analytes of clinical interest, using VITROS Immunodiagnostic Products Reagents.

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)

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Carol C Benson
Sign-Off

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