APR - 9 2007

1 510(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: K063720

1 Submitter Name, Address and Contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-4131

Contact Person: Sarah CV Parsons, RAC

2 Preparation Date

Date 510(k) prepared: December 14, 2006

3 Device Name

VITROS Immunodiagnostic Products Total β-hCG II Reagent Pack
VITROS Immunodiagnostic Products Total β-hCG II Calibrators
VITROS Immunodiagnostic Products Total β-hCG II Range Verifiers

Common Name: Total β-hCG II Assay

Classification Name(s): Human chorionic gonadotropin (HCG) test system (21 CFR 862.1155)
Calibrators (21 CFR 862.1150)
Quality Control material (assayed and unassayed) (21 CFR 862.1660)

Classifications: The Clinical Chemistry and Toxicology Panel of the FDA has placed the Human chorionic gonadotropin (HCG) test system as a Class II Medical Device.
The Microbiology Device Panel has classified Calibrators as Class II Medical Devices (21 CFR 862.1150).
The Microbiology Device Panel has classified Controls as Class I Medical Devices (21 CFR 862.1660)

Product Code: DHA, JIT, JJX

Manufacturing Establishment
Registration Number: 9680658

Manufacturer Site: Ortho Clinical Diagnostics, Inc.
Forest Farm Estate
Cardiff
United Kingdom
CF14 7YT

4 Predicate Device

Ortho-Clinical Diagnostics, Inc. believes that the VITROS Immunodiagnostic Products Total β-hCG II assay and VITROS Immunodiagnostic Products Total β-hCG II Range Verifiers are substantially equivalent to the Abbott Laboratories, ARCHITECT® SYSTEM Total β-HCG assay (K983424) and VITROS Immunodiagnostic Products Total β-hCG Range Verifiers (K970894).

5 Device Description

The VITROS Immunodiagnostic System uses luminescence as the signal in the quantitative and semi-quantitative determination of selected analytes in human body fluids, commonly serum and plasma. Coated microwells are used as the solid phase separation system.

The assay is comprised of three main elements:

1) The VITROS Immunodiagnostic Products range of immunoassay products in this case the VITROS Immunodiagnostic Products Total β-hCG II Reagent Pack, the VITROS Immunodiagnostic Products Total β-hCG II Calibrators, and the VITROS Immunodiagnostic Products Total β-hCG II Range Verifiers (which are combined by the VITROS Immunodiagnostic system to perform the VITROS Total β-hCG II assay).

2) The VITROS Immunodiagnostic System – instrumentation, which provides automated use of the immunoassay kits. The VITROS Immunodiagnostic System was cleared for market by a separate 510(k) pre-market notification (K962919).

3) Common reagents – used by the VITROS Immunodiagnostic System in each assay include the VITROS Immunodiagnostic Products Signal Reagent and VITROS Immunodiagnostic Products Universal Wash Reagent were cleared as part of the VITROS Immunodiagnostic Products Total T3 Reagent Pack and VITROS Immunodiagnostic Products Total T3 Calibrators 510(k) premarket notification (K964310).
Note: High Sample Diluent B was cleared as part of the VITROS Immunodiagnostic Products Total β-hCG Reagent Pack and VITROS

Immunodiagnostic Products Total β-hCG Calibrators 510(k) premarket notification (K970894).

The VITROS Immunodiagnostic System and common reagents are dedicated specifically for use only with the VITROS Immunodiagnostic Products range of immunoassay products.

6 Device Intended Use

VITROS Immunodiagnostic Products Total β-hCG II Reagent Pack
For quantitative measurement of human chorionic gonadotropin (hCG) and its β-subunit in human serum and plasma (EDTA or heparin) to aid in the early detection of pregnancy.

VITROS Immunodiagnostic Products Total β-hCG II Calibrators
For use in the calibration of the VITROS Immunodiagnostic System for the quantitative measurement of human chorionic gonadotropin (hCG) and its β-subunit in human serum and plasma (EDTA or heparin).

VITROS Immunodiagnostic Products Total β-hCG II Range Verifiers
For *in vitro* use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of human chorionic gonadotropin (hCG) and its β-subunit.

7 Comparison to Predicate Device

Ortho-Clinical Diagnostics, Inc. believes that the VITROS Immunodiagnostic Products Total β-hCG II assay and VITROS Immunodiagnostic Products Total β-hCG II Range Verifiers are substantially equivalent to the Abbott Laboratories, ARCHITECT® SYSTEM Total β-HCG assay (K983424) assay and VITROS Immunodiagnostic Products Total β-hCG Range Verifiers (K973517).
Tables 1 through 4 compare the VITROS Immunodiagnostic Products Total β-hCG II assay and Range Verifiers to the Abbott Laboratories, ARCHITECT® SYSTEM Total β-HCG II assay and VITROS Immunodiagnostic Products Total β-hCG Range Verifiers.

Table 1 **Comparison of the VITROS Immunodiagnostic Products Total β-hCG II assay to the Abbott Laboratories, ARCHITECT® SYSTEM Total β-HCG assay: Similarities**

Similarities		
Device Characteristic	**New device**	**Predicate device**
Intended Use	For the quantitative measurement of human chorionic gonadotropin (hCG) and its β-subunit in human serum and plasma (EDTA and heparin)	… for the quantitative and qualitative determination of beta-human chorionic gonadotropin (β-hCG) in human serum and plasma …
Basic principle	chemiluminescent immunometric assay	Chemiluminescent Microparticle Immunoassay
Antibody	conjugated monoclonal mouse anti-β-hCG	Conjugated monoclonal mouse anti-β-hCG
Sample type	Serum and Plasma (EDTA and heparin)	Serum and Plasma (EDTA and heparin)
Expected Values	**LMP n Min Max 2.5 97.5** 1-10 112 44.71 256,740 63.7 150,854 11-15 43 11,556 265,380 11,795 151,996 16-20 50 7,480.8 111,954 9,383.8 61,410 23-40 45 1,531.1 101,566 1,737.2 98,576	**LMP n Min Max 2.5 97.5** 1-10 50 <1.20 >225,000.00 201.6 >225,000.00 11-1 50 16,995.65 >225,000.00 22,536.49>225,000.00 16-20 50 8,860.23 >225,000.00 8,006.62 50,238.60 23-40 50 1,583.40 65,911.30 1,599.80 49,412.65
Measuring Range	Up to 15,000 mIU/mL	Up to 15,000 mIU/mL
Precision	Within-Run (CV 1.1-2.5%), Within-lab (2.9-4.2%)	Within-Run (CV 1.2-4.7%), Total (CV 1.6-4.9%)
Analytical Sensitivity	0.70 mIU/mL	≤ 1.2 mIU/mL
Specificity	≤ 10% for FSH, LH and TSH	≤ 10% for FSH, LH and TSH

Table 2 **Comparison of the VITROS Immunodiagnostic Products Total β-hCG II assay to the Abbott Laboratories, ARCHITECT® SYSTEM Total β-HCG assay: Differences**

Differences		
Device Characteristic	**New device**	**Predicate device**
Intended Use	Indication not in statement.	… for the early detection of pregnancy
Sample volume	40 µL	75 µL
Antibodies	Biotin conjugated mouse monoclonal anti-β-hCG	Mouse monoclonal anti-β-hCG coated microparticles.
Luminescent label	Horse radish peroxidase	acridinium
Instrumentation	VITROS Immunodiagnostic System	ARCHITECT SYSTEM
Calibrator levels	Three levels	Six levels

Table 3 **Comparison of the VITROS Immunodiagnostic Products Total β-hCG II Range Verifiers to the VITROS Immunodiagnostic Products Total β-hCG Range Verifiers: Similarities**

Similarities		
Device Characteristic	**New device**	**Predicate device**
Intended Use	For *in vitro* use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of human chorionic gonadotropin (hCG) and its β-subunit	For *in vitro* use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of human chorionic gonadotropin (hCG) and its β-subunit
Levels	Low and High	Low and High
Format	Freeze-dried	Freeze-dried

Table 4 **Comparison of the VITROS Immunodiagnostic Products Total β-hCG II Range Verifiers to the VITROS Immunodiagnostic Products Total β-hCG Range Verifiers: Differences**

Differences		
Device Characteristic	**New device**	**Predicate device**
Matrix	Human plasma	Bovine serum
Antigen	Bacterial Recombinant hCG	Purified from human urine hCG

8 Conclusions

The data presented in the premarket notification provide a reasonable assurance that the VITROS Total β-hCG II Reagent Pack, VITROS Total β-hCG II Calibrator and VITROS Total β-hCG II Range Verifiers are safe and effective for the stated intended uses and is substantially equivalent to the cleared predicate devices.

The VITROS Immunodiagnostic Products Total β-hCG II Reagent Pack and the VITROS Immunodiagnostic Products Total β-hCG II Calibrator were compared to the Abbott Laboratories, ARCHITECT® SYSTEM Total β-HCG assay. The VITROS Immunodiagnostic Products Total β-hCG II Range Verifiers were compared to the VITROS Immunodiagnostic Products Total β-hCG Range Verifiers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Sarah CV Parsons, RAC
Ortho-Clinical Diagnostics, Inc.
Regulatory Affairs, MC00881
100 Indigo Creek Drive
Rochester, NY 14626-5101

Re: k063720
Trade/Device Name: Vitros Immunodiagnostic Products Total B-HCG II reagent PA
Vitros Immunodiagnostic Products Total B-HCG II Calibrators
Vitros Immunodiagnostic Products Total B-HCG II Range Verifiers
Regulation Number: 21 CFR § 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: DHA, JIT, JJX
Dated: March 26, 2007
Received: March 27, 2007

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) 276-0490. 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

1 Indications for Use

510(k) Number (if known): K063720

Device Name: VITROS Immunodiagnostic Products Total β-hCG II Reagent Pack
VITROS Immunodiagnostic Products Total β-hCG II Calibrators
VITROS Immunodiagnostic Products Total β-hCG II Range Verifiers

Indications for Use:

For quantitative measurement of human chorionic gonadotropin (hCG) and its β-subunit in human serum and plasma (EDTA or heparin) to aid in the early detection of pregnancy.

For use in the calibration of the VITROS Immunodiagnostic System for the quantitative measurement of human chorionic gonadotropin (hCG) and its β-subunit in human serum and plasma (EDTA or heparin).

For *in vitro* use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of human chorionic gonadotropin (hCG) and its β-subunit.

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)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K063720