SEP 14 2006

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: K060678

1 Submitter Name, Address and Contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-3154

Contact Person: Sarah CV Parsons, RAC

2 Preparation Date

Date 510(k) prepared: March 13, 2006

3 Device Name

VITROS Immunodiagnostic Products Anti-HAV Total Reagent Pack
VITROS Immunodiagnostic Products Anti-HAV Total Calibrators
VITROS Immunodiagnostic Products Anti-HAV Total Controls

Common Name: Anti-HAV Total Assay
Anti-HAV Total Controls

Classification Name: Hepatitis A virus (HAV) serological assays (866.3310)

Single (specified) analyte controls (assayed and unassayed (862.1660

Assay Class: II special controls
Controls Class: I

4 Predicate Device

The VITROS Immunodiagnostic Products Anti-HAV Total assay is substantially equivalent to the IMX HAVAB 2.0 assay (PMA P780012).

The VITROS Immunodiagnostic Products Anti-HAV Total Controls is substantially equivalent to Blackhawk BioSystems, Inc. Virotrol II (BK960085).

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 system is comprised of three main elements:

- The VITROS Immunodiagnostic Products range of immunoassay products (in this case the VITROS Immunodiagnostic Products Anti-HAV Total Reagent Pack and the VITROS Immunodiagnostic Products Anti-HAV Total Calibrators) and VITROS Immunodiagnostic Products High Sample Diluent B which are combined by the VITROS Immunodiagnostics System to perform the VITROS Anti-HAV Total assay.

- 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).

- Common reagents used by the VITROS System in each assay. 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 System and common reagents are dedicated specifically for use only with the VITROS Immunodiagnostic Products range of immunoassay products.

The VITROS Anti-HAV Total assay utilizes a competitive assay design for the measurement of antibody to HAV Total (IgG and IgM). The competitive assay technique is used which involves pre-incubation of anti-HAV in the sample with HAV antigen in the Assay Reagent followed by incubation with a Conjugate Reagent that contains biotinylated mouse monoclonal anti-HAV antibody and horseradish peroxidase (HRP)-labeled mouse monoclonal anti-HAV antibody. The immune complex is captured

by streptavidin on the wells, unbound materials are removed by washing. The bound HRP conjugate is measured by a luminescent reaction. A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent, is added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. The electron transfer agent (a substituted acetanilide) increases the level of light produced and prolongs its emission. The light signals are read by the VITROS System. The binding of HRP is indicative of the absence anti-HAV antibody.

The VITROS Immunodiagnostic Products Anti-HAV Total Controls is comprised of two levels of human plasma that have been targeted to produce negative or positive results when used with the VITROS Immunodiagnostic Products Anti-HAV Total assay.

Control 1 (Negative)
Anti-HAV negative normal human plasma obtained from donors who were tested individually and found to be negative for hepatitis B surface antigen (HBsAg), and for antibodies to human immunodeficiency virus (HIV 1+2) and hepatitis C virus (HCV) using FDA approved methods (enzyme immunoassays, EIA).

Control 2 (Positive)
Normal human plasma spiked with anti-HAV Total positive plasma. Both plasmas were obtained from donors who were tested individually and found to be negative for HBsAg and antibodies to human immunodeficiency virus (HIV 1+2) and hepatitis C virus (HCV) using FDA approved methods (EIA).

6 Device Intended Use

VITROS Anti-HAV Total Reagent Pack:
For the *in vitro* qualitative detection of total antibody (IgG and IgM) to hepatitis A virus (total anti-HAV) in human adult and pediatric serum or plasma (EDTA, heparin or citrate using the VITROS ECi/ECiQ Immunodiagnostic System.

VITROS Anti-HAV Total Calibrator
For *in vitro* use in the calibration of the VITROS Immunodiagnostic System for the qualitative detection of antibodies to hepatitis A virus (anti-HAV) in human serum and plasma (EDTA, heparin or citrate).

VITROS Anti-HAV Total Controls
For *in vitro* use in monitoring the performance of the VITROS Immunodiagnostic System when used for the detection of antibodies to Hepatitis A virus (anti-HAV).

7 Comparison to Predicate Device

The VITROS Immunodiagnostic Products Anti-HAV Total Reagent Pack and VITROS Immunodiagnostic Products Calibrators are substantially equivalent to IMX HAVAB 2.0 assay which was approved by FDA (P780012) for IVD use.

The VITROS Immunodiagnostic Products Anti-HAV Total Controls is substantially equivalent to Blackhawk BioSystems, Inc Virotrol II which was cleared by FDA (BK960085) for IVD use.

Table 1.1 Comparison of the VITROS Immunodiagnostic Products Anti-HAV Total assay to the IMX HAVAB 2.0 assay: Similarities

Similarities		
Device Characteristic	**New Device**	**Predicate Device**
Intended Use	For the qualitative detection of total antibody (IgG and IgM) to hepatitis A virus (total anti-HAV) in serum and plasma	.....is a qualitative microparticle enzyme immunoassay for the detection of total antibody to hepatitis A virus.
Basic principle	Enzyme Immuno Assay	Enzyme Immuno Assay
Antigen	Hepatitis A virus	Hepatitis A virus
Instrumentation	Automated analyzer: ECi Immunodiagnostic System	Automated analyzer: IMX System
Sample type	Serum, plasma (heparin, citrate, EDTA)	Serum, plasma (heparin, citrate, EDTA)

Table 1.2 Comparison of the VITROS Immunodiagnostic Products Anti-HAV Total assay to the IMX HAVAB-2.0 assay: Differences

Differences		
Device Characteristic	**New Device**	**Predicate Device**
Antibody	Mouse anti-HAV monoclonal antibody	Human anti-HAV antibody
Tracer	Horseradish Peroxidase	Alkaline Phosphatase
Sample volume	10µL	150µL

Table 1.3 Comparison of the VITROS Immunodiagnostic Products Anti-HAV Total Controls to the Blackhawk BioSystems, Inc. Virotrol II Controls: Similarities

Similarities		
Device Characteristic	**New device**	**Predicate device**
Intended use	For *in vitro* use in monitoring the performance of the VITROS Immunodiagnostic System when used for the qualitative detection of antibodies to Hepatitis A virus (anti-HAV).	For use with assay procedures for the determination of antibodies to Hepatitis A virus (HAV)
Matrix of controls	Human plasma and antimicrobial agents	Human serum with added human proteins and antimicrobial agents

Table 1.4 Comparison of the VITROS Immunodiagnostic Products Anti-HAV Total Controls to the Blackhawk BioSystems, Inc. Virotrol II Controls: Differences

Differences		
Device Characteristic	**New device**	**Predicate device**
Intended Use	Only for the detection of antibodies to HAV	Can be used for the determination of antibodies to hepatitis B surface antigen (HBs)
Control level	Positive and negative	Positive
Expected values	Each control has a quoted mean value derived from a minimum of 10 assays and a standard deviation anticipated for single determinations of each control in a number of different laboratories using different reagent lots. Values are lot specific.	There is no assigned value. The VIROTROL II reagents have been designed to produce a positive reaction when used in the proper manner with many commercial test kits.

Precision was tested across three sites demonstrating total precision to be less than 6.7%. Precision of serum and plasma were also assessed supporting that there is no substantial difference based on samples matrix. A variety of common interferents and potential cross reactive subgroup were tested supporting that the samples do not interfere with the assay. Both IgG and IgM are detected and immunoglobulin in samples from post HAV vaccination subjects support the assay can be used distinguish an individual as a vaccine candidate.

Expected results of the VITROS Anti-HAV Total assay to detect IgG and IgM in presumably healthy individuals were determined from a US population residing in areas of high (Western, US) and low (Eastern US) HAV disease prevalence. The population represented the typical demographics of age, gender and race representative of the United States.

A multi-center study was conducted to establish the performance characteristics of the VITROS Anti-HAV Total assay using samples obtained in the U.S. and India from individuals at high risk for hepatitis and/or with signs or symptoms of hepatitis.

The overall positive percent agreement among the combined prospective samples was 99.74%. The overall negative percent agreement was 96.49%.

The VITROS Anti-HAV Total assay was positive in 100.0% of samples from subjects known to be anti-HAV IgM reactive. When compared to a reference anti-HAV assay, the percent agreement was 96.1% (74/77) as three subjects were negative for HAV in the reference assay.

The positive percent agreement of samples from pediatric subjects at low risk for hepatitis was 93.75%. The negative percent agreement was 97.85%.

8 Conclusions

The VITROS Immunodiagnostic Products Anti-HAV Total assay was compared to the Abbott IMX HAVAB 2.0 assay testing commercially available reagents and human samples.

The data presented in the premarket notification provide a reasonable assurance that the VITROS Anti-HAV Total assay and the VITROS Anti-HAV Total Controls are safe and effective for the stated intended use and is substantially equivalent to the cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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SEP 14 2006

Re: k060678
Trade/Device Name: VITROS Immunodiagnostic Products Anti-HAV Total Reagent Pack
VITROS Immunodiagnostic Products Anti-HAV Total Calibrators
VITROS Immunodiagnostic Products Anti-HAV Total Controls
Regulation Number: 21 CFR 866.3310
Regulation Name: Hepatitis A virus (HAV) serological assays
Regulatory Class: Class II
Product Code: LOL
Dated: August 4, 2006
Received: August 7, 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.

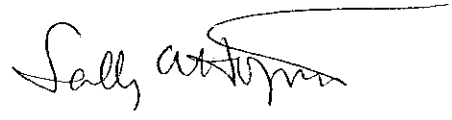
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



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Enclosure

510(k) Number (if known): k060678

Device Name: VITROS Immunodiagnostic Products Anti-HAV Total Reagent Pack
VITROS Immunodiagnostic Products Anti-HAV Total Calibrators
VITROS Immunodiagnostic Products Anti-HAV Total Controls

Indications for Use:

VITROS Anti-HAV Total Reagent Pack:

For the *in vitro* qualitative detection of total antibody (IgG and IgM) to hepatitis A virus (anti-HAV) in human adult and pediatric serum and plasma (EDTA, heparin or citrate) using the VITROS ECi/ECiQ Immunodiagnostic System.

The assay is indicated, in conjunction with other serological and clinical information, as an aid in the clinical laboratory diagnosis of individuals with acute or past hepatitis A virus infection, or as an aid in the identification of HAV-susceptible individuals prior to HAV vaccination. The detection of HAV-specific antibodies in human serum or plasma is laboratory evidence of acute or recent HAV infection.

VITROS Anti-HAV Total Calibrator

For *in vitro* use in the calibration of the VITROS Immunodiagnostic System for the qualitative detection of antibodies to hepatitis A virus (anti-HAV) in human serum and plasma (EDTA, heparin or citrate).

VITROS Anti-HAV Total Controls

For *in vitro* use in monitoring the performance of the VITROS Immunodiagnostic System when used for the detection of antibodies to Hepatitis A virus (anti-HAV).

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

510(k) k060673