SECTION 5: 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: k060770

1 Submitter Name, Address and Contact

Ortho-Clinical Diagnostics, Inc.
MC 881
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-3154

Contact Person: Sarah Parsons, RAC

2 Preparation Date

Date 510(k) prepared: March 20, 2006

3 Device Name

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

Common Name: Anti-HAV IgM Assay
Anti-HAV IgM 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 IgM assay is substantially equivalent to the IMX HAVAB-M assay (PMA P790019).

The VITROS Immunodiagnostic Products Anti-HAV IgM Controls is substantially equivalent to Blackhawk BioSystems, Inc Virotrol III (K974613).

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 IgM Reagent Pack and the VITROS Immunodiagnostic Products Anti-HAV IgM Calibrators) and VITROS Immunodiagnostic Products High Sample Diluent B which are combined by the VITROS Immunodiagnostics System to perform the VITROS Anti-HAV IgM 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 IgM assay utilizes an antibody class capture assay design, for the measurement of IgM antibodies to hepatitis A antigen, in human serum or plasma. The assay involves dilution of the sample and the simultaneous reaction of IgM in the diluted sample with biotinylated mouse monoclonal anti-human IgM antibody. The immune complex is captured by streptavidin on the wells, unbound materials are removed by washing. Horseradish peroxidase (HRP)-labeled mouse monoclonal anti-HAV antibody that has been complexed with inactivated HAV antigen (conjugate) is then captured by anti-HAV specific IgM bound to the wells. Unbound material is removed by washing. Enzyme substrate is then added and bound HRP conjugate is measured by a luminescent reaction. He binding of HRP conjugate is indicative of the presence of anti-HAV IgM.

6 Device Intended Use

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

VITROS Anti-HAV IgM Calibrator
For *in vitro* use in the calibration of the VITROS Immunodiagnostic System for the qualitative determination of IgM antibody to hepatitis A viral antigen (HAV) in human serum and plasma (EDTA, heparin or citrate.

VITROS Anti-HAV IgM Controls
For *in vitro* use in monitoring the performance of the VITROS Immunodiagnostic System when used for the detection of anti-HAV IgM.

7 Comparison to Predicate Device

The VITROS Immunodiagnostic Products Anti-HAV IgM Reagent Pack and VITROS Immunodiagnostic Products Calibrators are substantially equivalent to Abbott IMX HAVAB-M assay which was cleared by FDA (P790019) for IVD use.

The VITROS Immunodiagnostic Products Anti-HAV IgM Controls are substantially equivalent to Blackhawk BioSystems, Inc Virotrol III which was cleared by FDA (K974613) for IVD use.

Table 1 Comparison of the VITROS Immunodiagnostic Products Anti-HAV IgM assay to the IMX HAVAB-M assay: Similarities

Similarities		
Device Characteristic	**New Device**	**Predicate Device**
Intended Use	For the qualitative determination of IgM antibody to hepatitis A virus (anti-HAV IgM)...	For the qualitative determination of specific IgM antibody against hepatitis A virus (IgM Anti-HAV)
Basic principle	Enzyme Linked Immuno Assay	Enzyme Linked Immuno Assay
Antigen	Hepatitis A virus	Hepatitis A virus
Antibody	Monoclonal antibody: Mouse anti-HAV	Monoclonal antibody: Mouse anti-HAV
Instrumentation	ECi/ECiQ Immunodiagnostic System: Automated analyzer	IMX System: Automated analyzer
Sample type	Serum, plasma (heparin, citrate, EDTA)	Serum, plasma (heparin, citrate, EDTA)

Table 2 Comparison of the VITROS Immunodiagnostic Products Anti-HAV IgM assay to the IMX HAVAB-M assay: Differences

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

Table 3 Comparison of the VITROS Immunodiagnostic Products Anti-HAV IgM Controls to the Blackhawk BioSystems, Inc Virotrol III 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 detection of anti-HAV IgM.	… determination of immunoglobulin M antibodies to Hepatitis A Virus (HAV-IgM)…
Matrix of controls	Human plasma and antimicrobial agents	Human serum with added human proteins and antimicrobial agents
Control level	Positive and negative	Positive

Table 4 Comparison of the VITROS Immunodiagnostic Products Anti-HAV IgM Controls to the Blackhawk BioSystems, Inc Virotrol III Controls: Differences

Differences		
Device Characteristic	**New Device**	**Predicate Device**
Intended use	Only Anti-HAV IgM is detected in the positive control.	Both anti-HAV and anti-HBV IgM antibodies are included in the control
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 III reagents have been designed to produce a positive reaction when used in the proper manner with many commercial test kits. Levels of reactivity and specific performance characteristics will vary with different manufacturers' kits and assay procedures.

Summary of Performance

Precision was tested across three sites demonstrating total precision of a sample near the assay cutoff to be 13.2%. 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.

Expected results of the VITROS Anti-HAV IgM assay to detect 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 IgM 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 prospectively collected samples was 100.0% (32/32). The overall negative percent agreement was 99.74% (1156/1159).

The VITROS Anti-HAV IgM assay was also positive in 100.0% (77/77) of samples from subjects known to be anti-HAV IgM reactive, and negative in 100.0% (110/110) of samples from pediatric subjects at low risk for hepatitis.

8 Conclusions

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 15 2006

Ms. Sarah CV Parsons
Manager, Regulatory Affairs
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
MC0881
Rochester, NY 14626-5101

Re: k060770
Trade/Device Name: VITROS Immunodiagnostic Products Anti-HAV IgM Reagent Pack
VITROS Immunodiagnostic Products Anti-HAV IgM Calibrators
VITROS Immunodiagnostic Products Anti-HAV IgM Controls
Regulation Number: 21 CFR 866.3310
Regulation Name: Hepatitis A virus (HAV) serological assays
Regulatory Class: Class II
Product Code: LOL
Dated: August 3, 2006
Received: August 4, 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.

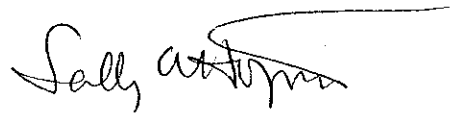
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): k060770

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

Indications for Use:

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

The assay is indicated for testing specimens from individuals who have signs and symptoms consistent with acute hepatitis. Assay results in conjunction with other clinical information, may be used for the laboratory diagnosis of individuals with acute or recent hepatitis A.

VITROS Anti-HAV IgM Calibrator
For *in vitro* use in the calibration of the VITROS Immunodiagnostic System for the qualitative determination of IgM antibody to hepatitis A viral antigen (HAV) in human serum and plasma (EDTA, heparin or citrate.

VITROS Anti-HAV IgM Controls
For *in vitro* use in monitoring the performance of the VITROS Immunodiagnostic System when used for the detection of anti-HAV IgM.

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