JAN 17 2003

2.0 General Information

2.1 510(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: _____

2.1.1 Submitter Name, Address, Contact

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

Contact Person: Sarah Parsons

2.1.2 Preparation Date

Date 510(k) Summary Prepared:

2.1.3 Device Name

Trade or Proprietary Name: *Vitros* Immunodiagnostic Products HBsAg Controls

Common Name: HBsAg Controls

Classification Name: 21CFR 862.1660 Quality Control Material (Assayed and Unassayed).

2.1.4 Predicate Device

The *Vitros* Immunodiagnostic Products HBsAg Controls are substantially equivalent to Ortho-Clinical Diagnostics, Inc. *Vitros* Immunodiagnostic Products HBsAg Controls (K011250).

2.1.5 Device Description

The *Vitros* Immunodiagnostic System uses luminescence as the signal in the qualitative detection of HBsAg in human plasma and serum. Coated microwells are used as the solid phase separation system.

The system is compromised of three main elements:

1. The *Vitros* Immunodiagnostic Products range of products, in this case *Vitros* Immunodiagnostic Products HBsAg Reagent Pack and *Vitros* Immunodiagnostic Products Calibrator, which are combined by the *Vitros* Immunodiagnostic System to perform a *Vitros* assay. The *Vitros* Immunodiagnostic Products HBsAg Reagent Pack and Calibrator have been approved for sale (PMA P000044).

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

3. Common reagents used by the *Vitros* System in each assay. The *Vitros* Immunodiagnostic Products Signal Reagent and the *Vitros* Immunodiagnostic Products Universal Wash Reagent were cleared as part of the *Vitros* Immunodiagnostic Products Total T3 510(k) pre-market notification (K964310).

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

2.1.6 Device Intended Use

The *Vitros* Immunodiagnostic Products HBsAg Controls are intended for use in monitoring the performance of the *Vitros* ECi Immunodiagnostic System when used for the *in vitro* qualitative detection of Hepatitis B Surface Antigen (HBsAg) in human serum and plasma (EDTA, heparin or citrate). The performance of the *Vitros* Immunodiagnostic Products HBsAg Controls has not been established with any other HBsAg assays.

2.1.7 Comparison to Predicate Device

The *Vitros* Immunodiagnostic Products HBsAg Controls are substantially equivalent to Ortho-Clinical Diagnostics Inc. *Vitros* Immunodiagnostic Products HBsAg Controls (K011250)

Table 1 lists the characteristics of the *Vitros* Immunodiagnostic Products HBsAg Controls (new device) and the *Vitros* Immunodiagnostic Products HBsAg Controls (predicate device).

Table 1. Comparison of New Device and Predicate Device

Device Characteristic	***Vitros* Immunodiagnostic Products HBsAg Controls (New device)**	***Vitros* Immunodiagnostic Products HBsAg Controls (Predicate device)**
Intended use	For use in monitoring the performance of the *Vitros* ECi Immunodiagnostic System when used for the *in vitro* qualitative detection of Hepatitis B Surface Antigen (HBsAg) in human serum **and plasma (EDTA, citrate and heparin).** The performance of the *Vitros* Immunodiagnostic Products HBsAg Controls has not been established with any other HBsAg assays.	For use in monitoring the performance of the *Vitros* ECi Immunodiagnostic System when used for the *in vitro* qualitative detection of Hepatitis B Surface Antigen (HBsAg) in human serum. The performance of the *Vitros* Immunodiagnostic Products HBsAg Controls has not been established with any other HBsAg assays.
Matrix of controls	Human serum with added constituents of human origin and antimicrobial agents	Human serum with added constituents of human origin and antimicrobial agents
Control level	Positive and negative	Positive and negative
Expected values	Each control has a quoted mean value derived form 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.	Each control has a quoted mean value derived form 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.

2.1.8 Summary of Assessment of Performance Data

The new device is the same as the predicate device with the addition of data that supports a modification in the Intended Use. Additional data demonstrate the use of the controls to assess the performance of the *Vitros* Immunodiagnostic Products HBsAg assay when determining the qualitative

detection of HBsAg in human plasma (EDTA, citrate and heparin) in addition to serum. Included in this 510(k) submission is the technical report that describes the assessment of multiple samples collected as either whole serum or in the presence of EDTA citrate or heparin. Each sample was tested either unspiked (negative) or spiked with known positive HBsAg plasma close to the weak positive detection level of the assay (positive). The results showed that all samples (serum, EDTA, citrate or heparin) behave similarly in the assay supporting that the controls can monitor the assay performance regardless of the tested sample matrix (serum or plasma).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 1 7 2003

Ms. Sarah Parsons
Associate, Regulatory Affairs
Ortho-Clinical Diagnostics, Inc.
Regulatory Affairs MC00882
100 Indigo Creek Drive
Rochester, NY 14626-5101

Re: k030067
Trade/Device Name: *Vitros* Immunodiagnostic Products HBsAg Controls
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed).
Regulatory Class: Class I
Product Code: MJX
Dated: January 6, 2003
Received: January 7, 2003

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 (301) 594-3084. 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

3.0 SUMMARY INFORMATION

3.1 Statement of Intended Use

510(k) Number (if known): K030067

Device Name: *Vitros* Immunodiagnostic Products HBsAg Controls

Indications for Use: For use in monitoring the performance of the *Vitros* ECi Immunodiagnostic System when used for the *in vitro* qualitative detection of Hepatitis B Surface Antigen (HBsAg) in human serum and plasma (EDTA, citrate and heparin). The performance of the *Vitros* Immunodiagnostic Products HBsAg Controls has not been established with any other HBsAg assays.

For *in vitro* diagnostic use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Freddie Tu-Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K030067

Prescription Use ✓ OR Over-The-Counter Use _____