2.0 GENERAL INFORMATION

OCT 3 1 2003

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: K032993

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 Anti-HBc IgM Controls

Common Name: Anti-HBc IgM Controls

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

2.1.4 Predicate Device

The *Vitros* Immunodiagnostic Products Anti-HBc IgM Controls are substantially equivalent to Blackhawk BioSystems, Inc Virotrol III (K974613).

2.1.5 Device Description

The *Vitros* Immunodiagnostic Products Anti-HBc IgM Controls are comprised of two levels of controls in separate vials:

Control 1 (Negative)

Normal human plasma obtained from donors who were tested individually and found to be negative for hepatitis B surface antigen, 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-HBc IgM positive plasma. The positive plasma was obtained from donors who were tested individually and found to be negative for antibodies to human immunodeficiency virus (HIV 1+2) and hepatitis C virus (HCV) using FDA approved methods (EIA).

Both controls contain antimicrobial agent and are freeze-dried.

The controls are assigned values from a minimum of 10 assays. The standard deviation is that which would be anticipated for single determinations of each control in a number of different laboratories using different reagent batches.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 31 2003

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

Re: k032993
Trade/Device Name: *Vitros* Immunodiagnostic Products Anti-HBc IgM Controls
Regulation Number: 21 CFR 866.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: September 24, 2003
Received: September 25, 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

2.2 Indications for Use Statement

510(k) Number (if known): K032993

Device Name: *Vitros* Immunodiagnostic Products Anti-HBc IgM Controls

Indications for Use: The *Vitros* Immunodiagnostic Products Anti-HBc IgM Controls are intended for use in monitoring the performance of the *Vitros* ECi Immunodiagnostic System when used for the *in vitro* qualitative detection of IgM antibody to Hepatitis B core antigen (anti-HBc IgM) in human serum and plasma (heparin, EDTA or citrate).
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)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Freddie M. Poole
Division Sign-Off

(Optional Format 1-2-96)

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032993