

MAY 19 1998

## Chapter 1 – Summary Information

### 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: K990016.

#### 1. Submitter name, address, contact

Ortho-Clinical Diagnostics, Inc.  
100 Indigo Creek Drive  
Rochester, New York 14626-5101  
(716) 453-3790

Contact Person: Anne Zavertnik

Date 510(k) prepared: December 31, 1998

#### 2. Device Name

Trade or Proprietary Name: VITROS Immunodiagnostic Products Anemia Controls  
Common Name: Anemia controls  
Classification Name: 21CFR 862.1660 Quality Control Material (Assayed and Unassayed)..

#### 3. Predicate Device

The VITROS Immunodiagnostic Products Anemia controls are substantially equivalent to Bio-Rad Lyphocheck® Immunoassay Plus Control Levels 1, 2 and 3 (K981532).

#### 4. 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, plasma and urine. Coated microwells are used as the solid phase separation system.

The system is comprised of three main elements:

1. The VITROS Immunodiagnostic Products range of products, in this case VITROS Immunodiagnostic Products Reagent Pack, VITROS Immunodiagnostic Products Calibrators which are combined by the VITROS Immunodiagnostic System to perform a VITROS assay.

## 510(k) Summary, continued.

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 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 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.

### 5. Device Intended Use

The VITROS Anemia Controls are intended for *in vitro* use in monitoring the performance of the VITROS Immunodiagnostic System when used for the measurement of selected analytes.

### 6. Comparison to Predicate Device

The VITROS Immunodiagnostic Products Anemia Controls is substantially equivalent to Bio-Rad Lyphochek® Immunoassay Plus Control Levels 1, 2 and 3 which was cleared by FDA (K981532) for IVD use.

Table 1 lists the similarities and differences of the device characteristics between the VITROS Anemia Controls and the predicate device.

**Table 1** List of the controls characteristics

Characteristics	New Device	Predicate Device
Intended use	For use in monitoring the performance of the VITROS System when used for the measurement of selected analytes	For use as an assayed quality control serum to monitor the precision of laboratory testing procedures
Matrix of controls	Composed of buffer and horse serum, spiked with different analytes to achieve the required levels	Human serum with added constituents of human origin and pure chemicals
Control levels	Low, medium and high	Low, medium and high

## 510(k) Summary, continued.

Table 1, (continued)

Characteristics	New Device	Predicate Device
Expected values	Each control has quoted for each specific analyte a mean value derived from a minimum of 10 assays and a standard deviation anticipated for singleton determinations of each control in a number of different laboratories using different reagent batches. Values are lot specific.	The mean values and acceptable ranges printed in the insert were derived from replicate analyses and are specific for this lot of Bio-Rad Lyphochek® Immunoassay Plus Control Levels 1, 2 and 3. The tests listed were performed by the reagent manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this control lot.

### 7. Conclusions

The data presented in the pre-market notification demonstrate that the VITROS Anemia Controls are substantially equivalent to the predicate device Bio-Rad Lyphochek® Immunoassay Plus Control Levels 1, 2 and 3 which was cleared by FDA (K981532) for IVD use.

The data presented in the premarket notification provide a reasonable assurance that the VITROS Anemia Controls are safe and effective for the stated intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

MAY 21 1999

Ms. Anne Zavertrnik  
Regulatory Affairs Associate  
Ortho-Clinical Diagnostics  
A Johnson & Johnson Company  
100 Indigo Creek Drive  
Rochester, New York 14626-5101

Re: K990016  
Trade Name: VITROS Immunodiagnostic Products Anemia Controls  
Regulatory Class: I  
Product Code: JJY  
Dated: March 26, 1999  
Received: March 31, 1999

Dear Ms. Zavertrnik:

This corrects the letter dated May 19, 1999 where the incorrect K#, K990916, was referenced. We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

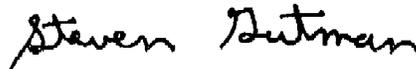
Page 2

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 I. Gutman, M.D, M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

