3/12/99

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: K990531.

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: February 17, 1999

2. Device Name

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

3. Predicate Device

The VITROS Immunodiagnostic Products Oncology controls are substantially equivalent to Scantibodies SYSCON Tumor Markers Controls Levels 1and 2 (K955812).

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.

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 Oncology 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 Oncology Controls is substantially equivalent to Scantibodies SYSCON Tumor Markers Controls Levels 1and 2 which was cleared by FDA (K955812) for IVD use.

Table 1 lists the similarities and differences of the device characteristics between the VITROS Oncology 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	A human based control used to monitor analytical procedures and reagents for detecting tumor markers in patient serum specimens
Matrix of controls	Human serum with added constituents of human origin and antimicrobial agents	Human serum with added constituents of human origin and stabilizers
Control levels	normal, mildly abnormal and grossly abnormal	normal and abnormal

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 printed in the insert were derived from replicate analyses from the method referenced and are specific for the lot of the Scantibodies SYSCON Tumor Marker Controls, Levels 1 and 2. Acceptable ranges may be defined using two standard deviations of the designated concentration for each analyte based on the mean values determined by each laboratory.

7. Conclusions

The information presented in the pre-market notification demonstrate that the VITROS Oncology Controls are substantially equivalent to the predicate device Scantibodies SYSCON Tumor Marker Controls Levels 1 and 2 which was cleared by FDA (K955812) for IVD use.

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

Statement of Accuracy of Foreign Language Translations

Statement

Translations for the package inserts and labeling are provided and verified as being accurate by individual regulatory contacts in each of the appropriate countries prior to their release.

It is the policy of Ortho-Clinical Diagnostics to ensure the accuracy of foreign language translations of package inserts and labeling for all products. All new literature is circulated to regulatory personnel for verification of accuracy of translation. We can therefore confirm that foreign language translations of the package insert for VITROS Oncology Controls accurately reflect the English language version.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 12 1999

Anne Zavertnik
Regulatory Affairs Associate
Ortho-Clinical Diagnostics
100 Indigo Creek Drive
Rochester NY 14626-5101

Re: K990531
Trade Name: VITROS Immunodiagnostic Products Oncology Controls
Regulatory Class: I
Product Code: JJY
Dated: February 17, 1999
Received: February 19, 1999

Dear Ms. Zavertnik:

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 (Premarket 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.

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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

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

Statement of Intended Use

510(k) Number (if known): K990531

Device Name: VITROS Immunodiagnostic Products Oncology Controls

Indications for Use: For *in vitro* use in monitoring the performance of the VITROS Immunodiagnostic System when used for the measurement of selected analytes.

Peter E Madsen

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990531

(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)

(Optional Format 1-2-96)