FEB 2 1999

1 ADMINISTRATIVE

1.1 510(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: K983690.

1. Submitter name, address, contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(716) 453-3607

Contact Person: Anne Zavertnik

Date 510(k) prepared: October 19, 1998

2. Device Name

Trade or Proprietary Name: VITROS Immunodiagnostic Products CA 15-3 Calibrators
VITROS Immunodiagnostic Products CA 15-3 Reagent Pack
Common Name: CA 15-3 assay
Classification Name: test for the *in vitro* quantitative determination of DF3-defined antigen in serum or plasma.

3. Comparitor Device

The VITROS Immunodiagnostic Products CA 15-3 assay is substantially equivalent to the Centocor CA 15-3 RIA (K963803).

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 and plasma. Coated microwells are used as the solid phase separation system.

The system is comprised of three main elements:

1. The VITROS Immunodiagnostic Products (in this case VITROS Immunodiagnostic Products CA 15-3 Reagent Pack, VITROS Immunodiagnostic Products CA 15-3 Calibrators, which are combined by the VITROS Immunodiagnostic System to perform the VITROS CA 15-3 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 (K984310).

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®CA 15-3 is an *in vitro* assay intended for the quantitative measurement of DF3 defined antigen in serum or plasma (EDTA or heparin) from patients previously treated for stage II or stage III breast cancer. Serial test results obtained with the VITROS CA 15-3 assay, in patients who are clinically free of disease, should be used in conjunction with all relevant information derived from diagnostic test, physical examination and full medical history in accordance with appropriate patient management procedures used for early detection of recurrence. The test is also intended for use as an aid in the management of breast cancer patients with metastatic disease by monitoring progression or response to treatment.

6. Comparison to Comparitor Device

The VITROS Immunodiagnostic Products CA 15-3 assay is substantially equivalent to Centocor CA 15-3 RIA (comparitor device), which was approved by FDA (K963803) for IVD use.

The relationship between the VITROS CA 15-3 assay and the comparitor device, determined by Bablock Passing regression, is:
VITROS CA 15-3 assay = 0.945 x [Centocor CA 15-3 RIA] + 1.55 (U/mL), with a correlation coefficient of 0.978.

Comparisons of the VITROS CA 15-3 assay and the comparitor device were performed with samples from a variety of clinical categories.

In addition to the studies mentioned above, tests were performed to obtain analytical sensitivity, specificity, precision, dilution and expected values. Refer to the VITROS CA 15-3 assay package insert for VITROS CA 15-3 assay results.

Table 1 lists the similarities and differences of the device characteristics between the VITROS CA 15-3 assay with the comparitor device, Centocor CA 15-3 RIA assay:

Table 1 List of the assay characteristics

Device Characteristic	VITROS CA 15-3 assay	Comparitor Device
Calibration range	0 - 500 U/mL	0 - 200 U/mL
Basic principle	Solid phase immunoassay	Solid phase radioimmunoassay
Tracer	Enzyme labeled	Radioactive tracer
Sample type	Serum, plasma (heparin or EDTA)	Serum, plasma
Antibody	1) Mouse monoclonal anti-DF3 antigen antibody in biotinylated antibody reagent 2) Mouse monoclonal anti-DF3 antigen antibody in conjugate reagent	1) Mouse monoclonal 115D8 antibody coated onto beads 2) Mouse monoclonal DF3 antibody labeled with I^{125}
Sample volume	10 µL	20 µL
Incubation time and temperature	First incubation 16 minutes at 37°C with shaking Second incubation 16 minutes at 37°C with shaking	First incubation 2 hours at room temperature Second incubation 3 hours at room temperature

7. Conclusions

The data presented in the premarket notification demonstrate that the VITROS CA 15-3 assay performs substantially equivalent to the cleared comparitor device.

Equivalence was demonstrated using currently commercially available reagents along with patient specimens from patients who are normal, undergoing therapeutic and/or undergoing diagnostic evaluation. In clinical studies of apparently healthy individuals, patients with cancer and patients with a variety of non-malignant diseases, the VITROS CA 15-3 assay exhibited distribution results that parallel expected distributions for these patient types.

The serial monitoring study demonstrated the clinical utility of the VITROS CA 15-3 assay for monitoring for recurrence of disease in patients previously treated for stage II or stage III breast cancer and for monitoring response to treatment of breast cancer patients with metastatic disease.

The data presented in the premarket notification provide a reasonable assurance that the VITROS CA 15-3 assay is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 1999

Anne Zavertnik
Regulatory Affairs Associate
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101

Re: K983690
Trade Name: VITROS Immunodiagnostic Products CA 15-3 Calibrators
VITROS Immunodiagnostic Products CA 15-3 Reagent Pack
Regulatory Class: II
Product Code: MOI
Dated: December 14, 1998
Received: December 16, 1998

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 (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
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.3 Indications For Use Statement

510(k) Number (if known): K983690

Device Name: VITROS Immunodiagnostic Products CA 15-3 Reagent Pack
VITROS Immunodiagnostic Products CA 15-3 Calibrators

Indications for Use: The VITROS®CA 15-3 is an *in vitro* assay intended for the quantitative measurement of DF3 defined antigen in serum or plasma (EDTA or heparin) from patients previously treated for stage II or stage III breast cancer. Serial test results obtained with the VITROS CA 15-3 assay, in patients who are clinically free of disease, should be used in conjunction with all relevant information derived from diagnostic test, physical examination and full medical history in accordance with appropriate patient management procedures used for early detection of recurrence. The test is also intended for use as an aid in the management of breast cancer patients with metastatic disease by monitoring progression or response to treatment.

Peter G. Maxim

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983690

(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)