JUN 1 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: K990943.

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: March 19, 1999

2. Device Name

Trade or Proprietary Name: VITROS® Immunodiagnostic Products CEA Calibrators
VITROS® Immunodiagnostic Products CEA Reagent Pack
Common Name: CEA assay
Classification Name: test for the *in vitro* quantitative determination of carcinoembyronic antigen in serum or plasma.

3. Predicate Device

The VITROS Immunodiagnostic Products CEA assay is substantially equivalent to the Abbott AxSYM CEA Assay (P830066).

4. Device Description

The VITROS ECi Immunodiagnostic System uses luminescence as the signal in the quantitative and semi-quantitative determination of selected analytes in human body fluids, commonly serum, plasma or urine. 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 CEA Reagent Pack, VITROS Immunodiagnostic Products CEA Calibrators, which are combined by the VITROS ECi System to perform the VITROS CEA assay).

2. The VITROS ECi Immunodiagnostic System - instrumentation, which provides automated use of the immunoassay kits. The VITROS ECi 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*® CEA is an *in vitro* assay intended for the quantitative measurement of carcinoembyronic antigen (CEA) in human serum and plasma (EDTA or heparin) to aid in the prognosis and management of cancer patients in whom changing concentrations of CEA are observed.

6. Comparison to Predicate Device

The VITROS Immunodiagnostic Products CEA assay is substantially equivalent to Abbott AxSYM CEA Assay (predicate device), which was approved by FDA (P830066) for IVD use.

The relationship between the VITROS CEA assay and the predicate device, determined by Passing and Bablok, is:
VITROS CEA assay = 1.06 x [Abbott AxSYM CEA assay] + 0.124 (ng/mL), with a correlation coefficient of 0.977.

Comparisons of the VITROS CEA assay and the predicate 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 CEA assay package insert for VITROS CEA assay results.

Table 1 lists the similarities and differences of the device characteristics between the VITROS CEA assay with the predicate device:

Table 1 List of the assay characteristics

Device Characteristic	VITROS CEA assay	Predicate Device
Calibration range (reportable range)	0 - 400 ng/mL	0.5 - 500ng/mL
Basic principle	Solid phase immunoassay	Solid phase immunoassay
Sample type	Serum, plasma (heparin or EDTA)	Serum, plasma (heparin or EDTA)
Antibody	1) mouse monoclonal anti-CEA in biotinylated antibody reagent 2) mouse monoclonal anti-CEA in conjugate reagent	1) mouse monoclonal anti-CEA coated Microparticles 2) mouse monoclonal anti-CEA in conjugate reagent
Sample volume	20 µL	150 µL
Analytical sensitivity	0.3 ng/mL	0.5 ng/mL

7. Conclusions

The data presented in the premarket notification demonstrate that the VITROS CEA assay performs substantially equivalent to the approved predicate 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 malignant disease and patients with a variety of non-malignant diseases, the VITROS CEA assay exhibited distribution results that parallel expected distributions for these patient types.

The serial monitoring study demonstrated that the VITROS CEA assay is substantial equivalent to the predicate device in patients previously treated for colorectal cancer.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 1 1999

Anne Zavertnik
Regulatory Affairs Associate
ORTHO-CLINICAL DIAGNOSTICS, INC.
100 Indigo Creek Drive
Rochester, New York 14626-5101

Re: K990943
Trade Name: VITROS® Immunodiagnostic Products CEA Calibrators
VITROS® Immunodiagnostic Products CEA Reagent Pack
Regulatory Class: II
Product Code: DHX
Dated: March 19, 1999
Received: March 22, 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 (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

1.2 Indications For Use Statement

510(k) Number (if known): K990943

Device Name: VITROS Immunodiagnostic Products CEA Reagent Pack
VITROS Immunodiagnostic Products CEA Calibrators

Indications for Use: The *Vitros*® CEA is an *in vitro* assay intended for the quantitative measurement of carcinoembryonic antigen (CEA) in human serum and plasma (EDTA or heparin) to aid in the prognosis and management of cancer patients in whom changing concentrations of CEA are observed.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Madsen

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990943

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

(Optional Format 1-2-96)