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: K 983031.

1. Submitter name, address, contact

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

Contact Person: Charles Morganson

Date 510(k) prepared: August 27, 1998

2. Device Name

Trade or Proprietary Name: VITROS Immunodiagnostic Products AFP assay
Common Name: Alpha-Fetoprotein assay
Classification Name: Alpha-Fetoprotein test kit for testicular cancer

3. Predicate Device

The VITROS Immunodiagnostic Products AFP assay is substantially equivalent to the Abbott AxSYM System AFP (P820060S8).

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

The system is comprised of three main elements:
The VITROS Immunodiagnostic Products (in this case VITROS Immunodiagnostic Products AFP Reagent Pack, VITROS Immunodiagnostic Products AFP Calibrators, which are combined by the VITROS Immunodiagnostic System to perform the VITROS AFP assay).

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).

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 AFP assay is intended for the *in vitro* quantitative measurement of alpha-fetoprotein (AFP) in human serum, to aid in the management of patients with non-seminomatous testicular cancer.

6. Comparison to Predicate Device

The VITROS Immunodiagnostic Products AFP assay is substantially equivalent to Abbott AxSYM System AFP (predicate device), which was approved by FDA (P820060S8) for IVD use.

The relationship between the VITROS AFP assay and the predicate device, determined by Deming's Regression, is:
VITROS AFP assay = 0.889 x [AxSYM AFP assay] + 2.60 (IU/mL), with a correlation coefficient of 0.991.

Comparisons of the VITROS AFP assay and the predicate device were performed with samples from serially monitored patients diagnosed and treated for testicular cancer.

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

Table 1 lists the similarities and differences of the device characteristics between the VITROS AFP assay with the predicate device, Abbott AxSYM AFP assay:

Table 1 List of the assay characteristics

Device Characteristic	VITROS AFP assay	Predicate Device
Calibration range	0 - 500 IU/mL (1st IRP 72/225) 0 - 520 ng/mL	0 - 350 ng/mL
Basic principle	Solid phase immunoassay	Solid phase immunoassay
Tracer	Enzyme labeled	Enzyme labeled
Instrumentation	VITROS Immunodiagnostic System	Abbott AxSYM System
Sample type	Serum	Serum, plasma (heparin, citrate or EDTA)
Antibody	1) Sheep polyclonal anti-AFP antibody in biotinylated antibody reagent 2) Mouse monoclonal anti-AFP antibody in conjugate reagent	1) mouse monoclonal anti-AFP antibody coated onto microparticles 2) mouse monoclonal anti-AFP antibody in conjugate
Sample volume	25 µL	150 µL
Incubation time and temperature	First incubation 16 minutes at 37°C with shaking Second incubation 16 minutes at 37°C with shaking	Details not listed in package insert

7. Conclusions

The data presented in the premarket notification demonstrate that the VITROS AFP assay performs substantially equivalent to the predicate device, for which there is an approved PMA.

Equivalence was demonstrated using currently commercially available reagents along with patient specimens covering the normal, therapeutic and diagnostic range. In clinical studies of apparently healthy individuals, patients with cancer and patients with a variety of non-malignant diseases, the VITROS AFP assay exhibited distribution results that parallel expected distributions for these patient types.

The serial monitoring study demonstrated the clinical utility of the VITROS AFP assay as an aid in the management of patients with non-seminomatous testicular cancer.

The data presented in the premarket notification provide a reasonable assurance that the VITROS AFP 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

DEC 18 1998

Ortho-Clinical Diagnostics, Inc.
C/O Mr. Charles Morganson, Jr.
Regulatory Affairs Associate
Regulatory Affairs MC00882
100 Indigo Creek Drive
Rochester, New York 14626

Re: K983031
Trade Name: Vitros Immunodiagnostic Products AFP Reagent Pack
Regulatory Class:
Product Code: LOJ
Dated: August 27, 1998
Received: August 31, 1998

Dear Mr. Morganson:

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.

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): K983031

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

Indications for Use: VITROS AFP Reagent Pack - For the *in vitro* quantitative measurement of alpha-fetoprotein (AFP) in human serum to aid in the management of patients with non-seminomatous testicular cancer.

VITROS AFP Calibrators - For *in vitro* use in the calibration of the VITROS Immunodiagnostic System for the quantitative measurement of AFP in human serum.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Maker

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983031

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

(Optional Format 1-2-96)