

MAY 14 1999

VITROS CA 125 II assay

K983875

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: K983875.

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: October 29, 1998

2. Device Name

Trade or Proprietary Name: VITROS Immunodiagnostic Products CA 125 II Calibrators
VITROS Immunodiagnostic Products CA 125 II Reagent Pack

Common Name: CA 125 II assay

Classification Name: test for the *in vitro* quantitative determination of OC 125 defined antigen in serum or plasma.

3. Predicate Device

The VITROS Immunodiagnostic Products CA 125 II assay is substantially equivalent to the Boehringer Mannheim Elecsys CA 125 II (K972162).

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 125 II Reagent Pack, VITROS Immunodiagnostic Products CA 125 II Calibrators, which are combined by the VITROS Immunodiagnostic System to perform the VITROS CA 125 II assay).

VITROS CA 125 II 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® CA 125 II is an *in vitro* assay intended for the quantitative measurement of OC 125 defined antigen in the serum or plasma (EDTA or heparin). The *Vitros* CA 125 II assay is to be used as an aid in monitoring response to therapy for patients with epithelial ovarian cancer. Serial testing for patient CA 125 assay values should be used in conjunction with other clinical methods used for monitoring ovarian cancer.

6. Comparison to Predicate Device

The VITROS Immunodiagnostic Products CA 125 II assay is substantially equivalent to Boehringer Mannheim Elecsys CA 125 II (predicate device), which was cleared by FDA (K972162) for IVD use.

The relationship between the VITROS CA 125 II assay and the predicate device, determined by Bablock Passing regression, is:

VITROS CA 125 II assay = $0.963 \times [\text{Boehringer Mannheim Elecsys CA 125 II}] + 0.654$ (U/mL), with a correlation coefficient of 0.946.

Comparisons of the VITROS CA 125 II 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 CA 125 II assay package insert for VITROS CA 125 II assay results.

Table 1 lists the similarities and differences of the device characteristics between the VITROS CA 125 II assay with the predicate device:



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 14 1999

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

Re: K983875
Trade Name: VITROS Immunodiagnostic Products CA 125 II
Calibrators
VITROS Immunodiagnostic Products CA 125 II Reagent
Pack
Regulatory Class: II
Product Code: LTK
Dated: February 22, 1999
Received: February 24, 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.

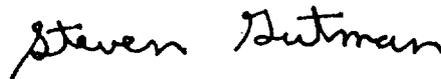
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large, prominent "S" and "G".

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

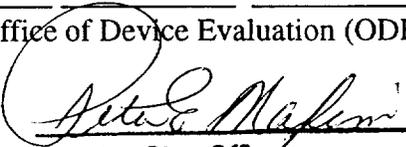
510(k) Number (if known): K983875

Device Name: VITROS Immunodiagnostic Products CA 125 II Reagent Pack
VITROS Immunodiagnostic Products CA 125 II Calibrators

Indications for Use: The Vitros® CA 125 II is an *in vitro* assay intended for the quantitative measurement of OC 125 defined antigen in the serum or plasma (EDTA or heparin). The *Vitros* CA 125 II assay is to be used as an aid in monitoring response to therapy for patients with epithelial ovarian cancer. Serial testing for patient CA 125 assay values should be used in conjunction with other clinical methods used for monitoring ovarian cancer.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983875

Prescription Use ✓
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

(Optional Format 1-2-96)