

1. 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: K983990.

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: November 6, 1998

2. Device Name

Trade or Proprietary Name: VITROS Immunodiagnostic Products Cortisol assay

Common Name: Cortisol assay

Classification Name: CORTISOL assay for the *in vitro* quantitative measurement of cortisol in human serum, plasma (heparin or EDTA) or urine.

3. Predicate Device

The VITROS Immunodiagnostic Products Cortisol assay is substantially equivalent to ABBOTT TDx Cortisol assay.

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 (in this case VITROS Immunodiagnostic Products Cortisol Reagent Pack, VITROS Immunodiagnostic Products CORTISOL Calibrators, and VITROS Immunodiagnostic Products Metabolism Controls, which are combined by the VITROS Immunodiagnostic System to perform the VITROS Cortisol assay).

510K Summary, Continued

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, VITROS Immunodiagnostic Products Universal Wash Reagent and VITROS Immunodiagnostic High Sample Diluent B 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 CORTISOL assay is intended for the *in vitro* quantitative measurement of cortisol in human serum or plasma (EDTA or heparin) or urine.

6. Comparison to Predicate Device

The VITROS Immunodiagnostic Products Cortisol assay is substantially equivalent to Abbott TDx Cortisol assay (predicate device), which was approved by FDA (K854419) for IVD use.

The relationship between the VITROS Cortisol assay and the predicate device, determined by Deming's Regression, is:

$$\text{VITROS Cortisol assay} = 0.83 \times \text{Abbott TDx Cortisol assay} - 16.1 \text{ nmol/L}$$

Comparisons of the VITROS Cortisol assay and the predicate device were performed with samples from a variety of clinical categories.

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

Table 1 lists the similarities and differences of the device characteristics between the VITROS CORTISOL assay with the predicate device, Abbott TDx Cortisol assay.

Table 1 List of the assay characteristics

Device Characteristic	VITROS CORTISOL assay	Predicate Device
Calibration range	3 - 1700 nmol/L	3- 1655 nmol/L
Basic principle	Solid phase immunoassay	Solid phase immunoassay
Tracer	Enzyme labeled	Fluorescein labeled

57

510K Summary, Continued

Table 1 (continued)

Device Characteristic	VITROS CORTISOL assay	Predicate Device
Instrumentation	VITROS Immunodiagnostic System	Abbott TDx
Sample type	Serum, plasma (EDTA or heparin) or urine	Serum, plasma or urine
Antibody	Sheep polyclonal anti-cortisol antibody biotinylated antibody reagent.	Mouse monoclonal and Goat polyclonal anti-cortisol antibody reagent.

7. Conclusions

The data presented in the pre-market notification demonstrate that the VITROS Cortisol assay performs substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using currently commercially available reagents along with patient specimens covering a variety of clinical categories.

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

js



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 29 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Anne Zavertnik
Regulatory Affairs Associate
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Canal Ponds
Rochester, NY 14626-5101

Re: K983990
Trade Name: Vitros Immunodiagnostic Products Cortisol Assay
Regulatory Class: II
Product Code: CGR
Dated: December 8, 1998
Received: December 9, 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 (Pre-market 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.

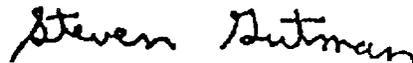
Page 2

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 I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2

Statement of Intended Use

Page 1 of 1

510(k) Number (if known): K 983990

Device Name: VITROS Immunodiagnostic Products Cortisol Reagent Packs
and VITROS Immunodiagnostic Products Cortisol Calibrators.

VITROS Immunodiagnostic Products Metabolism Controls

Indications for Use:

For *in vitro* quantitative measurement of cortisol in human serum, plasma (EDTA or heparin) or urine.

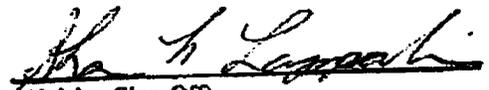
For *in vitro* use in monitoring the performance of the VITROS Immunodiagnostic System when used for the measurement of cortisol in human serum, plasma (EDTA or heparin) or urine.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983990
Over-The-Counter Use

(Optional Format 1-2-96)

3