

NOV 4 1998

16983507

## Appendices

### 510(k) Summary (Appendix A)

---

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: K983507.

#### 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: September 21, 1998

#### 2. Device Name

Trade or Proprietary Name: VITROS Immunodiagnostic Products TESTOSTERONE assay  
Common Name: Testosterone assay  
Classification Name: TESTOSTERONE assay for the *in vitro* quantitative measurement of testosterone in human serum and plasma (EDTA or heparin).

#### 3. Predicate Device

The VITROS Immunodiagnostic Products TESTOSTERONE assay is substantially equivalent to DPC Coat-A-Count Testosterone assay (K813401).

#### 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 TESTOSTERONE Reagent Pack, VITROS Immunodiagnostic Products TESTOSTERONE Calibrators, which are combined by the VITROS Immunodiagnostic System to perform the VITROS TESTOSTERONE assay).

---

Continued on next page

## 510(k) Summary (Appendix A), 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 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 TESTOSTERONE assay is intended for the *in vitro* quantitative measurement of testosterone in human serum or plasma (EDTA or heparin).

### 6. Comparison to Predicate Device

The VITROS Immunodiagnostic Products TESTOSTERONE assay is substantially equivalent to DPC Coat-A-Count Testosterone assay (predicate device), which was approved by FDA (K813401) for IVD use.

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

VITROS TESTOSTERONE assay =  $0.9222 \times$  DPC Coat-A-Count Testosterone assay – 2.25 nmol/L

Comparisons of the VITROS TESTOSTERONE 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 TESTOSTERONE assay package insert for VITROS TESTOSTERONE assay results.

Table 1 lists the similarities and differences of the device characteristics between the VITROS TESTOSTERONE assay with the predicate device, DPC Coat-A-Count Testosterone assay.

---

*Continued on next page*

## 510(k) Summary (Appendix A), Continued

**Table 1** List of the assay characteristics

Device Characteristic	VITROS TESTOSTERONE assay	Predicate Device
Calibration range	0 – 75 nmol/L	0.7 – 55 nmol/L
Basic principle	Solid phase immunoassay	Solid phase immunoassay
Tracer	Enzyme labeled	Radio labeled
Instrumentation	VITROS Immunodiagnostic System	Microwell plate reader
Sample type	Serum, plasma (EDTA or heparin)	Serum, plasma (heparin)
Antibody	Mouse monoclonal anti-testosterone antibody biotinylated antibody reagent.	Polyclonal anti-testosterone antibody coated onto polypropylene tubes.
Sample volume	25 µL	50 µL
Incubation time and temperature	16 minutes at 37° C	3 hours at 37° C

### 7. Conclusions

The data presented in the pre-market notification demonstrate that the VITROS TESTOSTERONE assay performs substantially equivalent to the predicate device, for which there is FDA clearance.

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

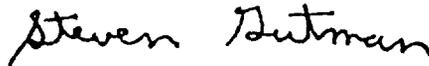
The data presented in the premarket notification provide a reasonable assurance that the VITROS TESTOSTERONE assay is safe and effective for the stated intended use.



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

Enclosure

# Statement of Intended Use (Appendix D)

510(k) Number (if known): K983507

Device Name: VITROS Immunodiagnostic Products Testosterone Reagent Pack  
VITROS Immunodiagnostic Products Testosterone Calibrators  
VITROS Immunodiagnostic Products Testosterone Controls

Indications for Use: For the *in vitro* quantitative measurement of testosterone in human serum and plasma (EDTA or heparin).  
  
For *in vitro* use in the calibration of the *Vitros* Immunodiagnostic System for the quantitative measurement of testosterone in human serum and plasma (EDTA or heparin).  
  
For *in vitro* use in monitoring the performance of the *Vitros* Immunodiagnostic System when used for the measurement of testosterone.

(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

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K983507