NOV 3 1998

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: 983513.

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 Range Verifiers; VITROS Immunodiagnostic Products NTx Range Verifiers.
Common Name: Range Verifiers
Classification Name: VITROS Range verifiers for use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of immunoassays which include Testosterone and NTx.

3. Predicate Device

The VITROS Immunodiagnostic Products Testosterone and NTx Range Verifiers are substantially equivalent to VITROS Immunodiagnostic Products FSH Range Verifiers (K973517).

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

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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

For *in vitro* use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of immunoassays which include Testosterone and NTx.

6. Comparison to Predicate Device

The VITROS Immunodiagnostic Products Range Verifiers are substantially equivalent to VITROS FSH Range Verifiers (predicate device), which was approved by FDA (K973517) for IVD use.

Table 1 lists the similarities and differences of the device characteristics between the VITROS TESTOSTERONE Range Verifiers with the predicate device, VITROS FSH Range Verifiers.

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Table 1 List of the assay characteristics

Device Characteristic	VITROS Range Verifiers	Predicate Device
Intended use	For use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of a particular analyte (see page 6 for a list of analytes).	For use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of FSH.
Matrix of Range Verifiers	A base matrix of freeze-dried human plasma or buffered matrix spiked with analyte (see page 6 for full details).	A base matrix of freeze-dried human plasma spiked with human pituitary FSH.
Range Verifier levels	Low and high	Low and high

7. Conclusions

The data presented in the pre-market notification demonstrate that the VITROS Testosterone and NTx Range Verifiers are substantially equivalent to the predicate device, for which there is FDA clearance.

Equivalence was demonstrated by comparing the physical properties and intended uses of these devices with commercially available reagents.

The data presented in the premarket notification provide a reasonable assurance that the VITROS Testosterone and NTx Range Verifiers are 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

NOV 3 1998

Ms. Anne Zavertnik
Regulatory Affairs Associate
Ortho-Clinical Diagnostics
A Johnson & Johnson Company
100 Indigo Creek Drive
Rochester, New York 14626-5101

Re: K983513
Trade Name: VITROS Immunodiagnostic Products Range Verifiers
Regulatory Class: I
Product Code: JJY
Dated: October 6, 1998
Received: October 7, 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 (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

Statement of Intended Use (Appendix C)

510(k) Number (if known): K983513

Device Name: VITROS Immunodiagnostic Products Range Verifiers

Indications for Use: For *in vitro* use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of immunoassays which include Testosterone and NTx.

(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 K983513

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

(Optional Format 1-2-96)