JAN 29 1999

Update: December 23, 1998

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: K983674.

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: October 19, 1998

2. Device Name

Trade or Proprietary Name: VITROS Immunodiagnostic Products NTx assay
Common Name: NTx assay
Classification Name: NTx assay for the *in vitro* quantitative measurement of cross linked N-telopeptides of type I collagen (NTx) in human urine.

3. Predicate Device

The VITROS Immunodiagnostic Products NTx assay is substantially equivalent to the Osteomark NTx Test (K980518)

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

510(k) 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 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 NTx assay is intended for the *in vitro* quantitative measurement of cross linked N-telopeptides of type I collagen (NTx) in human urine as an indicator of human bone resorption.

6. Comparison to Predicate Device

The VITROS Immunodiagnostic Products NTx assay is substantially equivalent to Osteomark NTx test (predicate device), which was approved by FDA (K980518) for IVD use.

The relationship between the VITROS NTx assay and the predicate device, determined by Deming's Regression, is:
VITROS NTx assay = 0.957 x Osteomark NTx test + 6.5 (nM BCE/mM creatinine)
Comparisons of the VITROS NTx 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 NTx assay package insert for VITROS NTx assay results.

Table 1 lists the similarities and differences of the device characteristics between the VITROS NTx assay with the predicate device, Osteomark NTx test.:

510(k) Summary, continued

Table 1 List of the assay characteristics

Device Characteristic	VITROS NTx assay	Predicate Device
Calibration range (Reportable Range)	0 – 3000 nM BCE	20 – 3000 nM BCE
Basic principle	Solid phase immunoassay	Solid phase immunoassay
Tracer	Enzyme labeled	Enzyme labeled
Instrumentation	VITROS Immunodiagnostic System	Microwell plate reader
Sample type	Urine	Urine
Antibody	Mouse monoclonal anti-NTx antibody in conjugate reagent	Mouse monoclonal anti-NTx antibody in conjugate reagent
Sample volume	25 µL	25 µL
Incubation time and temperature	30 minutes at 37° C	18-28° C for 90 minutes (± 5 minutes).

7. Conclusions

The data presented in the pre-market notification demonstrate that the VITROS NTx 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 NTx 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

JAN 29 1999

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

Re: K983674
Trade Name: VITROS Immunodiagnostic Products NTx assay
Regulatory Class: I
Product Code: JMM
Dated: December 23, 1998
Received: December 28, 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.

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,

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 D)

510(k) Number (if known): K983674

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

Indications for Use:

Vitros NTx Reagent Pack – For *in-vitro* quantitative measurement of cross linked N-telopeptides of type I collagen (NTx) in human urine as an indicator of human bone resorption. A single NTx value cannot provide the rate of bone resorption as reported results do not contain a measure of time. Use of this test has not been established in primary hyperparathyroidism or hyperthyroidism.

Vitros NTx Calibrators – For *in-vitro* use in the calibration of the VITROS Immunodiagnostic System for the quantitative measurement of NTx in human urine.

Vitros NTx Controls – For *in-vitro* use in the monitoring of the performance of the VITROS Immunodiagnostic System when used for the quantitative measurement of NTx in human urine.

Jan Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983674

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)