OCT 8 1999

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: K992360.

1. Submitter name, address, contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(716) 453-4041

Contact Person: Marlene Shulman

2. Preparation date

Date 510(k) prepared: 14th July 1999

3. Device name

Trade or Proprietary Name:
VITROS Immunodiagnostic Products Troponin I Reagent Pack
VITROS Immunodiagnostic Products Troponin I Calibrators

Common Name : TROPONIN I assay
Classification Name: Immunoassay Method, Troponin Subunit

4. Predicate device

The VITROS Immunodiagnostic Products Troponin I Reagent Pack and VITROS Immunodiagnostic Products Troponin I Calibrators are substantially equivalent to the DADE Dimension™ RxL Cardiac Troponin-I (TROP) Method.

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5. 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 range of immunoassay products (in this case VITROS Immunodiagnostic Products Troponin I Reagent Pack, VITROS Immunodiagnostic Products Troponin I Calibrators, which are combined by the VITROS Immunodiagnostic System to perform the VITROS Troponin I assay, and VITROS Immunodiagnostic Products High Sample Diluent B).
   Note: High sample Diluent B was cleared as part of the VITROS Immunodiagnostic Products Total β-hCG Reagent Pack and VITROS Immunodiagnostic Products Total β-hCG Calibrators 510(k) premarket notification (K970894).

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 Reagent Pack and VITROS Immunodiagnostic Products Total T3 Calibrators 510(k) premarket notification (K964310).

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5. Device description, Continued	The VITROS System and common reagents are dedicated specifically for use only with the VITROS Immunodiagnostic Products range of immunoassay products.
6. Device intended use	The VITROS Troponin I assay is intended for the *in vitro* quantitative measurement of Troponin I (cTnI) in human serum or plasma (EDTA or heparin), to aid in the diagnosis of myocardial infarction.
7. Comparison to predicate device	The VITROS Immunodiagnostic Products Troponin I Reagent Pack and VITROS Immunodiagnostic Products Troponin I Calibrators are substantially equivalent to the DADE Dimension RxL Cardiac Troponin-I (TROP) Method which was cleared by the FDA (K973650) for IVD use. The relationship between the VITROS Troponin I assay and the DADE Dimension RxL Cardiac Troponin-I assay, determined by Passing and Bablok Regression, is: VITROS Troponin I assay = 1.05 x X – 0.151 (ng/mL), with a Spearman rank correlation coefficient of 0.983, where X is DADE Dimension RxL Cardiac Troponin-I assay. This relationship was determined from a panel of patient samples from a variety of clinical categories. In addition to the above mentioned correlation study, studies were performed to determine the precision, analytical sensitivity, specificity and expected values of the VITROS Troponin I assay, (refer to the VITROS Troponin I Reagent Pack package insert for summaries of the results of these studies). Table 1 lists the characteristics of the assays performed using the VITROS Troponin I assay and the DADE Dimension RxL Cardiac Troponin-I Assay.

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7. **Comparison to predicate device,** Continued

Table 1

Device Characteristic	VITROS Troponin I assay	DADE Dimension RxL Cardiac Troponin-I
Calibration range	0-100 ng/mL	0-50 ng/mL
Basic principle	Solid phase immunoassay	Solid phase immunoassay
Tracer	Enzyme labeled	Enzyme labeled
Antibody	Mouse monoclonal anti-Troponin I antibody (Biotinylated antibody reagent). Goat polyclonal anti-Troponin I antibody (HRP-Conjugate reagent).	Mouse monoclonal anti-Troponin I antibody (in Antibody Tablets and Conjugate).
Instrumentation	VITROS Immunodiagnostic System	DADE Dimension RxL clinical chemistry system
Sample type	Serum and plasma (EDTA or heparin).	Serum and plasma (heparin).
Sample volume	50µL	60µL
Incubation time and temperature	8 minutes at 37°C	5.4 minutes at 37°C

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8. Conclusions

The data presented in the pre-market notification demonstrate that the performance of the VITROS Troponin I assay is substantially equivalent to the cleared predicate device.

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 8 1999

Ms. Marlene A. Shulman
Regulatory Affairs Associate
Ortho-Clinical Diagnostics
100 Indigo Creek Drive
Rochester, New York 14626-5101

Re: K992366
Trade Name: VITROS Immunodiagnostic Products Troponin I Reagent Packs
VITROS Immunodiagnostic Products Troponin I Calibrators
Regulatory Class: II
Product Code: MMI
Dated: September 22, 1999
Received: September 23, 1999

Dear Ms. Shulman:

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

510(k) Number (if known): K992366

Device Name: VITROS Immunodiagnostic Products Troponin I Reagent Pack

VITROS Immunodiagnostic Products Troponin I Calibrators

Indications for Use: For the *in vitro* quantitative measurement of Troponin I (cTnI) in human serum or plasma (EDTA or heparin), to aid in the diagnosis of myocardial infarction.

For use in the calibration of the *Vitros* Immunodiagnostic System for the quantitative measurement of cardiac Troponin I (cTnI) in human serum and plasma (EDTA or heparin).

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992366

(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)