K031031

SEP 2 9 2003

1.0 GENERAL INFORMATION

1.1 510(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 _____.

1.1.1. Submitter Name, Address, Contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-4152

Contact Person: Ann M Quinn

1.1.2. Preparation Date

Date 510(k) prepared: March 31, 2003

1.1.3. 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: Troponin I (cTnI) Test System

1.1.4. 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.

1.1.5. Device Description

The *Vitros* Troponin I assay is performed using the *Vitros* Troponin I Reagent Pack and *Vitros* Immunodiagnostic Products Troponin I Calibrators on the *Vitros* ECi Immunodiagnostic System with Intellicheck ™ . An immunometric technique is used. Cardiac Troponin I present in the sample reacts simultaneously with a biotinylated antibody (mouse monoclonal anti-cTnI) and a horseradish peroxidase (HRP)-labeled antibody conjugate (affinity purified goat polyclonal anti-cTnI). The antigen-antibody complex is captured by streptavidin on the wells. Unbound materials are removed by washing. A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent (a substituted acetanilide) is added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. The electron transfer agent increases the level and duration of the light produced. The light signals are read by the *Vitros* ECi System. The amount of HRP conjugate bound is directly proportional to the concentration of cTnI present in the sample.

1.1.6. Device Intended Use

The *Vitros* Troponin I assay is intended for the *in vitro* quantitative measurement of Troponin I (cTnI) in human heparin plasma to aid in the diagnosis of myocardial infarction.

1.1.7. 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.

Additional data is being provided on hemoglobin interference and precision. A summary of this data is provided in the tables on the following pages.

Hemoglobin may interfere with the *Vitros* Troponin I assay. At a troponin level of 0.026 ng/mL, hemoglobin at 100, 250, and 500 mg/dL caused a positive bias of 0.043, 0.175 and 0.226 ng/mL respectively. At a troponin level of approximately 0.3 ng/mL, hemoglobin at 100, 250 and 500 mg/dL caused a positive bias of 0.029, 0.075 and 0.166 ng/mL respectively.

Interferent	Interferent Concentration		Units = ng/mL (µg/L)	
			Analyte Conc.*	Bias**
Hemoglobin	0.062 mmol/L	100 mg/dL	0.026	0.043
Hemoglobin	0.155 mmol/L	250 mg/dL	0.026	0.175
Hemoglobin	0.310 mmol/L	500 mg/dL	0.026	0.226
Hemoglobin	0.062 mmol/L	100 mg/dL	0.279	0.029
Hemoglobin	0.155 mmol/L	250 mg/dL	0.305	0.075
Hemoglobin	0.310 mmol/L	500 mg/dL	0.347	0.166

* Average test concentration of replicate determinations using one or two different lots of reagent.

** Estimate of the average difference observed

Precision at low Troponin I concentrations was evaluated to describe performance at Troponin I concentrations equal to, and below the AMI cutoff of 0.4 ng/mL (µg/L). Ten patient sample pools were assayed in singleton once per day on 11 different days over a 28 day period using a single reagent lot. Calibration was performed at the initiation of the data collection period. The precision profile was constructed using all of the pools above the analytical sensitivity. The data presented are provided as a guideline.

The SD observed at the URL of 0.08 ng/mL (µg/L) and at the AMI Cutoff of 0.4 ng/mL (µg/L) were 0.010 (12.0 %CV) and 0.024 (5.9% CV) ng/mL (µg/L), respectively. The lowest concentration at which the VITROS Troponin I assay achieved a 10% CV was 0.12 ng/mL (µg/L).

	Units = ng/mL (µg/L)		
	cTnI	Inter-assay Precision	
	ng/mL	SD	CV%
Upper Reference Limit (URL)	0.08	0.010	12.0
Lowest Concentration with 10% CV	0.12	0.012	10.0
AMI Cutoff	0.40	0.024	5.9

1.1.8 Conclusions

These additions provide data that continue to support the safe and effective use of the *Vitros* Troponin I Reagent Pack and Calibrators for use in quantitatively measuring Troponin I concentration in heparin plasma.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 2 9 2003

Ms. Ann M. Quinn, RAC
Manager, Regulatory Affairs
Ortho Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626-5101

Re: k031031
Trade/Device Name: *Vitros* Immunodiagnostic Products Troponin I Reagent Pack
Vitros Immunodiagnostic Products Troponin I Calibrators
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MMI; JIT
Dated: September 4, 2003
Received: September 5, 2003

Dear Ms Quinn.:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

1.2 Statement of Intended Use

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510(k) Number (if known):

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 heparin plasma 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 heparin plasma.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031031

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)