DEC 1 9 2006

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 k062838.

1. Submitter Name, Address, Contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-3730

Contact Person: Charlotte Baker

2. Preparation Date

Date 510(k) prepared: September 20, 2006

3. Device Name

Trade or Proprietary Names:
VITROS® Immunodiagnostic Products Troponin I ES Reagent Pack
VITROS® Immunodiagnostic Products Troponin I ES Calibrators
VITROS® Immunodiagnostic Products Troponin I ES Range Verifiers

Common Name:
Troponin I assay and controls

Classification Names:
Immunoassay Method, Troponin Subunit, (862.1215), Class II

Calibrator, multi-analyte mixture, (862.1150), Class II

Quality control material, (assayed and unassayed), (862.1660), Class I

4. Predicate Device

The VITROS® Immunodiagnostic Products Troponin I ES Reagent Pack and Calibrators (the VITROS Troponin I ES assay) are substantially equivalent to the BECKMAN Access® AccuTnI Troponin I assay (K974075).

The VITROS® Immunodiagnostic Products Troponin I ES Range Verifiers are substantially equivalent to the VITROS Troponin I Range Verifiers (K992349).

5. Device Description

1. The VITROS Immunodiagnostic Products range of immunoassay products: VITROS Immunodiagnostic Products Troponin I ES Reagent Pack, the VITROS Immunodiagnostic Products Troponin I ES Calibrators and the VITROS Immunodiagnostic Products Troponin I ES Range Verifiers, (which are combined by the VITROS Immunodiagnostic System to perform the VITROS Troponin I ES assay), and VITROS Immunodiagnostic Products High Sample Diluent B.

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).

Note: High Sample Diluent B was cleared as part of the VITROS Immunodiagnostic Products Total ß-hCG Reagent Pack and VITROS Immunodiagnostic Products Total ß-hCG Calibrators 510(k) premarket notification (K970894).

The VITROS Immunodiagnostic System and common reagents are dedicated specifically for use only with the VITROS Immunodiagnostic Products range of immunoassay products.

6. Device Intended Use

VITROS Troponin I ES Reagent Pack:
For *in vitro* diagnostic use only.
For the quantitative measurement of cardiac Troponin I (cTnI) in human serum and plasma (heparin and EDTA) using the VITROS Immunodiagnostic System, to aid in the assessment of myocardial damage and risk stratification.

Cardiac Troponin I measurement aids in the diagnosis of acute myocardial infarction and in the risk stratification of patients with non-ST-segment elevation acute coronary syndromes with respect to relative risk of mortality, myocardial infarction (MI) or increased probability of ischemic events requiring urgent revascularization procedures.

VITROS Troponin I ES Calibrators:
For *in vitro* diagnostic use only.
For use in the calibration of the VITROS Immunodiagnostic System for the quantitative measurement of cardiac Troponin I (cTnI) in human serum and plasma (heparin and EDTA).

VITROS Troponin I ES Range Verifiers:
For *in vitro* diagnostic use only.
For in vitro use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the quantitative measurement of cardiac Troponin I (cTnI).

7. Comparison to Predicate Device

The VITROS® Immunodiagnostic Products Troponin I ES Reagent Pack and Calibrators are substantially equivalent to the BECKMAN Access® AccuTnI Troponin I Reagent Pack and Calibrators (K974075).

The VITROS® Immunodiagnostic Products Troponin I ES Range Verifiers are substantially equivalent to the VITROS Troponin I Range Verifiers (K992349).

Table 1 (page 4) presents the similarities and differences of both assays.

Table 2 (page 5) presents the similarities and differences of both calibrators

Table 3 (page 5) presents the similarities and differences of both range verifiers.

Table 1 Comparison of the VITROS and BECKMAN Troponin I assays

Similarities		
Device Characteristic	**New Device-VITROS® Troponin I ES assay**	**Predicate Device-BECKMAN Access® AccuTnI Troponin I assay**
Intended Use	For the *in vitro* quantitative measurement of cardiac Troponin I (cTnI) in human serum and plasma (heparin and EDTA) using the VITROS Immunodiagnostic System, to aid in the *assessment of myocardial damage and risk stratification.* Cardiac Troponin I measurement *aids in the diagnosis of acute myocardial infarction and in the risk stratification* of patients with non-ST-segment elevation acute coronary syndromes with respect to relative risk of mortality, myocardial infarction (MI) or increased probability of ischemic events requiring urgent revascularization procedures.	For the *in vitro* quantitative determination of cardiac troponin I (cTnI) levels in human serum and plasma using the Access Immunoassay Systems to *aid in the diagnosis and treatment* of myocardial infarction and *cardiac muscle damage.* Cardiac troponin I determination *aids in the risk stratification* of patients with unstable angina or non-ST segment elevation acute coronary syndromes with respect to relative risk of mortality, myocardial infarction, or increased probability of ischemic events requiring urgent revascularization procedures.
Basic Principal	Chemiluminescence Immunoassay	Chemiluminescence Immunoassay
Tracer	Enzyme labeled	Enzyme labeled
Instrumentation	Automated Immunoassay System	Automated Immunoassay System
Antibody	Mouse monoclonal	Mouse monoclonal
Sample type	Serum and plasma (heparin and EDTA)	Serum and plasma (EDTA and heparin)
Organizations used/referenced	NACB, ESC/ACC/AHA, WHO	NACB, ESC/ACC/AHA, WHO
Lower Limit of Detection	0.012ng/mL	Not applicable
Differences		
Basic principle	Solid phase immunoassay	2-site immunoenzymatic assay
Sample volume	80µL	40µL
Measuring range	0.012-80.0 ng/mL	0.01-100 ng/mL
Analytical Sensitivity	<0.009 ng/mL	0.01 ng/mL
Hook Effect	None up to 14,000 ng/mL	None up to 1,920 ng/mL
Expected Values: 99th percentile URL	0.034 ng/mL	0.04 ng/mL
AMI Cut off	0.120 ng/mL (95% sens., 93% spec.)	0.50 ng/mL (96% sens., 94% spec.)
10% CV	0.034 ng/mL	0.06 ng/mL
Spec.& Sens over time (0 to 24 hrs.)	Sens. Range 69-90% Spec. Range 94-96%	Sens. Range 46-91% Spec. Range 96-88%
CLSI Standards Used or Referenced	C24, EP5, EP6, EP7, EP9, EP17, C28, GP10, H3, H4, M29	EP6-P, EP5-A, EP7-P

Table 2 Comparison of the VITROS and BECKMAN Troponin I Calibrators

Similarities		
Device Characteristic	**New Device-VITROS® Troponin I ES Calibrators**	**Predicate Device-BECKMAN Access® AccuTnI Troponin I Calibrators**
Intended Use	For use in the calibration of the VITROS Immunodiagnostic System for the quantitative measurement of cardiac Troponin I (cTnI) in human serum and plasma (heparin and EDTA).	Intended to calibrate the Access AccuTnI assay for the quantitative determination of cardiac troponin I (cTnI) levels in human serum and plasma using the Access Immunoassay Systems to aid in the diagnosis and treatment of myocardial infarction and cardiac muscle damage.
Calibrator Format	Liquid	Liquid
Differences		
Calibrator Levels	3	6

Table 3 Comparison of the VITROS Troponin I Range Verifiers

Similarities		
Device Characteristic	**New Device-VITROS® Troponin I ES Range Verifiers**	**Predicate Device-VITROS® Troponin I Range Verifiers**
Intended Use	For in vitro us in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of cardiac Troponin I (cTnI).	For in vitro us in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of cardiac Troponin I (cTnI).
Matrix of Range Verifiers	Human serum based matrix with antimicrobial agent	Human serum based matrix with bovine proteins and antimicrobial agent
Differences		
Range Verifier Levels	Low and High (0 & 80 ng/mL)	Low and High (0 & 95 ng/mL)
Format	Liquid	Freeze-dried

8. Conclusions

The data presented provide a reasonable assurance that the VITROS Immunodiagnostic Products Troponin I ES Reagent Pack, Calibrators and Range Verifiers are safe and effective for the stated intended uses and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Charlotte Baker
Regulatory Affairs Specialist
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Dr.
Rochester, NY 14626-5101

DEC 19 2006

Re: k062838
Trade/Device Name: VITROS Immunodiagnostic Products Troponin I ES Reagent Pack
VITROS Immunodiagnostic Products Troponin I ES Calibrator
VITROS Immunodiagnostic Products Troponin I ES Range Verifier
Regulation Number: 21 CFR§ 862.1215
21 CFR§ 862.1150
21 CFR§ 862.1660
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MMI, JIT, JJX
Dated: September 21, 2006
Received: September 26, 2006

Dear Ms. Baker:

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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): K062838

Device Names: VITROS® Immunodiagnostic Products Troponin I ES Reagent Pack
VITROS® Immunodiagnostic Products Troponin I ES Calibrators
VITROS® Immunodiagnostic Products Troponin I ES Range Verifiers

Indications for Use:

VITROS® Troponin I ES Reagent Pack:
For *in vitro* diagnostic use only.
For the quantitative measurement of cardiac Troponin I (cTnI) in human serum and plasma (heparin and EDTA) using the VITROS Immunodiagnostic System, to aid in the assessment of myocardial damage and risk stratification.

Cardiac Troponin I measurement aids in the diagnosis of acute myocardial infarction and in the risk stratification of patients with non-ST-segment elevation acute coronary syndromes with respect to relative risk of mortality, myocardial infarction (MI) or increased probability of ischemic events requiring urgent revascularization procedures.

VITROS® Troponin I ES Calibrators:
For *in vitro* diagnostic use only.
For use in the calibration of the VITROS Immunodiagnostic System for the quantitative measurement of cardiac Troponin I (cTnI) in human serum and plasma (heparin and EDTA).

VITROS® Troponin I ES Range Verifiers:
For *in vitro* diagnostic use only.
For in vitro use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the quantitative measurement of cardiac Troponin I (cTnI).

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K062838