JUN - 6 2006

Ortho-Clinical Diagnostics
a Johnson & Johnson company
100 Indigo Creek Drive
Rochester, New York 14626-5101

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: K060632

1 Submitter Name, Address and Contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-4131

Contact Person: Leah Van De Water

2 Preparation Date

Date 510(k) prepared: March 8, 2006

3 Device Name

VITROS Immunodiagnostic Products NT-proBNP Reagent Pack
Common Name: NT-proBNP Reagent Pack
Classification Name: B-Type natriuretic peptide test system (862.1117), Class II

VITROS Immunodiagnostic Products NT-proBNP Calibrators
Common Name: NT-proBNP Calibrators
Classification Name: Calibrator (862.1150), Class II

VITROS Immunodiagnostic Products NT-proBNP Range Verifiers
Common Name: NT-proBNP Range Verifiers
Classification: Quality control material (862.1660), Class I

4 Predicate Device

The VITROS Immunodiagnostic Products NT-proBNP Reagent Pack , VITROS Immunodiagnostic Product NT-proBNP Calibrators are substantially equivalent to the Roche Elecsys® proBNP Immunoassay K051382.

The VITROS Immunodiagnostic Products NT-proBNP Range Verifiers are substantially equivalent to the VITROS Immunodiagnostic Product CEA Range Verifiers previously cleared under K990984.

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 there main elements:

- The VITROS Immunodiagnostic Products range of immunoassay products in this case the VITROS Immunodiagnostic Products NT-proBNP Reagent Pack, the VITROS Immunodiagnostic Products NT-proBNP Calibrators, and the VITROS Immunodiagnostic Products NT-proBNP Range Verifiers (which are combined by the VITROS Immunodiagnostic system to perform the VITROS NT-proBNP assay) and VITROS Immunodiagnostic Products High Sample Diluent B.

- 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).

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

6 Device Intended Use

VITROS Immunodiagnostics NT-proBNP Reagent Pack:
For the *in vitro* quantitative measurement of N-terminal pro Brain Natriuretic Peptide (NT-proBNP) in human serum and plasma (EDTA or heparin) to aid in the diagnosis of congestive heart failure and for the risk stratification of acute coronary syndrome and congestive heart failure. The test is further indicated as an aid in the assessment of increased risk of cardiovascular events and mortality in patients at risk for heart failure who have stable coronary artery disease. The test can also be used in the assessment of heart failure severity in patients diagnosed with congestive heart failure.

VITROS Immunodiagnostic Products NT-proBNP Calibrator
For *in vitro* use in the calibration of the VITROS Immunodiagnostic System for the quantitative measurement of N-terminal pro Brain Natriuretic Peptide (NT-proBNP) in human serum and plasma (EDTA or heparin).

VITROS Immunodiagnostic Products NT-proBNP Range Verifiers
For the *in vitro* use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the quantitative measurement of N-terminal pro Brain Natriuretic Peptide (NT-proBNP).

7 Comparison to Predicate Device

The VITROS Immunodiagnostic Products NT-proBNP Reagent Pack and Calibrators is substantially equivalent to the Roche Elecsys proBNP Immunoassay K051382. The VITROS Immunodiagnostic Products NT-proBNP Range Verifiers are substantially equivalent to the VITROS Immunodiagnostic Products CEA Range Verifiers K990984.

Tables 1 through 3 compare the VITROS Immunodiagnostic Products NT-proBNP Reagent Pack, Calibrator and Range Verifier to the Roche Elecsys proBNP Immunoassay K051382 and VITROS Immunodiagnostic Products CEA Range Verifiers K990984.

Table 1 **Comparison of the VITROS Immunodiagnostic Products NT-proBNP Reagent Pack to the Elecsys proBNP Reagent Pack**

Comparison		
Device Characteristic	**VITROS (new device)**	**Elecsys (predicate device)**
Intended Use	For the *in vitro* quantitative measurement of N-terminal pro Brain Natriuretic Peptide (NT-proBNP) in human serum and plasma (EDTA or heparin) to aid in the diagnosis of congestive heart failure and for the risk stratification of acute coronary syndrome and congestive heart failure. The test is further indicated as an aid in the assessment of increased risk of cardiovascular events and mortality in patients at risk for heart failure who have stable coronary artery disease. The test can also be used in the assessment of heart failure severity in patients diagnosed with congestive heart failure.	For the *in vitro* quantitative determination of N-terminal pro-Brain natriuretic peptide in human serum and plasma. The Elecsys proBNP assay is used as an aid in the diagnosis of individuals suspected of have congestive heart failure. The test is further indicated for the risk stratifications of patients with acute coronary syndrome and congestive heart failure. The test may also serve as an aid in the assessment of increased risk of cardiovascular events and mortality in patients at risk for heart failure who have stable coronary artery disease.
Basic principle	Chemiluminescence Immunoassay	Electrochemiluminescence Immunoassay
Antibody	Biotinylated polyclonal anti-NT-proBNP (sheep)	Biotinylated polyclonal anti-NT-proBNP (sheep)

4.0: 510(k) Summary

Instrumentation	ECi/ECiQ Immunodiagnostic System: Automated analyzer	Elecsys family of analyzers (Elecsys 1010, Elecsys 2010 and Elecsys Modular Analytics Immunassay Analyzers
Sample type	Human serum and plasma (EDTA and heparin)	Human serum and plasma
Expected Values	• Age and sex-related statistics • Cut-offs of 125 pg/mL for patients younger than 75 years and 450 pg/mL for patients 75 years and older	• Age and sex-related statistics • Cut-offs of 125 pg/ml for patients younger than 75 years and 450 pg/mL for patients 75 years and older
Measuring Range	5.00-35,000 pg/mL	5-35,000 pg/mL
Hook Effect	No high dose hook effect up to 500,000 pg/mL	No high dose hook effect up to 300,000 pg/mL
Analytical Sensitivity	< 5.00 pg/mL	5 pg/mL
Functional Sensitivity	< 10.0 pg/mL	< 50 pg/mL

Table 2 **Comparison of the VITROS Immunodiagnostic Products NT-proBNP Calibrator to the Elecsys ® proBNP CalSet**

Comparison		
Device Characteristic	**VITROS (new device)**	**Elecsys (predicate device)**
Intended Use	For in vitro used in the calibration of the VITROS Immunodiagnostic System for the quantitative measurement of N-terminal pro Brain Natriuretic Peptide (NT-proBNP) in human serum and plasma (EDTA or heparin).	Elecsys proBNP Calset is used for calibrating the quantitative proBNP assay on the Elecsys 1010/2010 and MODULAR ANALYTICS E170 immunoassay systems
Matrix	Liquid; NT-proBNP in buffer with bovine serum albumin and antimicrobial agent	Lyophilized equine serum matrix with added synthetic NT-proBNP (1-76)
Levels	Cal 1 0 pg/mL Cal 2 150 pg/mL Cal 3 12,500 pg/mL	Cal 1 140 pg/mL Cal 2 2700 pg/mL

Table 3 Comparison of the VITROS Immunodiagnostic Products NT-proBNP Range Verifiers to the VITROS Immunodiagnostic Products CEA Range Verifiers

Comparison		
Device Characteristic	**VITROS (new device)**	**VITROS (predicate device)**
Intended Use	For in vitro use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the quantitative measurement of N-terminal pro Brain Natriuretic Peptide (NT-proBNP)	For in vitro use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of CEA.
Matrix	Liquid; Synthetic NT-proBNP in buffer with bovine serum albumin and antimicrobial agent	Liquid; Human CEA in buffer with bovine serum albumin and antimicrobial agent
Levels	Low and High	Low and High

10 Conclusions

The data presented in the premarket notification provide a reasonable assurance that the VITROS NT-proBNP Reagent Pack, VITROS NT-proBNP Calibrator and VITROS NT-proBNP Range Verifiers are safe and effective for the stated intended uses and is substantially equivalent to the cleared predicate devices.

The VITROS Immunodiagnostic Products NT-proBNP Reagent Pack and the VITROS Immunodiagnostic Products NT-proBNP Calibrator were compared to the Elecsys proBNP Immunoassay (K051382). The VITROS Immunodiagnostic Products NT-proBNP Range Verifiers were compared to the VITROS Immunodiagnostic Products CEA Range Verifiers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Leah Van De Water
Regulatory Affairs Associate
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Dr.
Rochester, NY 14626-5101

JUN - 6 2006

Re: k060632
Trade/Device Name: VITROS Immunodiagnostic Products NT-proBNP Reagent Pack
VITROS Immunodiagnostic Products NT-proBNP Calibrator
VITROS Immunodiagnostic Products NT-proBNP Range Verifier
Regulation Number: 21 CFR§ 862.1117
Regulation Name: B-type natriuretic peptide test system
Regulatory Class: Class II
Product Code: NBC, JIT, JJX
Dated: May 5, 2006
Received: May 8, 2006

Dear Ms. Water:

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

Indications for Use

510(k) Number (if known): K060632

Device Name:

VITROS Immunodiagnostic Products NT-proBNP Reagent Pack
VITROS Immunodiagnostic Products NT-proBNP Calibrator
VITROS Immunodiagnostic Products NT-proBNP Range Verifier

Indications for Use:

VITROS Immunodiagnostics NT-proBNP Reagent Pack:
For the *in vitro* quantitative measurement of N-terminal pro Brain Natriuretic Peptide (NT-proBNP) in human serum and plasma (EDTA or heparin) to aid in the diagnosis of congestive heart failure and for the risk stratification of acute coronary syndrome and congestive heart failure. The test is further indicated as an aid in the assessment of increased risk of cardiovascular events and mortality in patients at risk for heart failure who have stable coronary artery disease. The test can also be used in the assessment of heart failure severity in patients diagnosed with congestive heart failure.

VITROS Immunodiagnostic Products NT-proBNP Calibrator
For *in vitro* use in the calibration of the VITROS Immunodiagnostic System for the quantitative measurement of N-terminal pro Brain Natriuretic Peptide (NT-proBNP) in human serum and plasma (EDTA or heparin).

VITROS Immunodiagnostic Products NT-proBNP Range Verifiers
For the *in vitro* use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the quantitative measurement of N-terminal pro Brain Natriuretic Peptide (NT-proBNP).

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

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

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

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Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060632