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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: K033300

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: October 10, 2003

3. **Device name**

Trade or Proprietary Name:
Vitros Immunodiagnostic Products Myoglobin Reagent Pack
Vitros Immunodiagnostic Products Myoglobin Calibrators
Vitros Immunodiagnostic Products Myoglobin Range Verifiers

Common Name: Myoglobin assay
Classification Name: Immunoassay Method, Myoglobin (866.5680)
Class: II

4. **Predicate device**

a. The *Vitros* Immunodiagnostic Products Myoglobin assay is substantially equivalent to the DADE **Dimension** RxL Myoglobin (MYO) Method.

b. The *Vitros* Immunodiagnostic Products Myoglobin Range Verifiers are substantially equivalent to the *Vitros* Troponin I Range Verifiers.

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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: *Vitros* Immunodiagnostic Products Myoglobin Reagent Pack, the *Vitros* Immunodiagnostic Products Myoglobin Calibrators and the *Vitros* Immunodiagnostic Products Myoglobin Range Verifiers, (which are combined by the *Vitros* Immunodiagnostic System to perform the *Vitros* Myoglobin 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).

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

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510(k) Summary, Continued

6. Device intended use

a. The *Vitros* Myoglobin assay is intended for the *in vitro* quantitative measurement of myoglobin concentration in human serum or plasma (EDTA, or heparin) to aid in the diagnosis of myocardial infarction.

b. The *Vitros* Myoglobin Range Verifiers are intended for the assayed use in verifying the calibration range of the *Vitros* Immunodiagnostic System when used for the measurement of Myoglobin. For *in vitro* use.

7. a. Comparison to predicate device: ***Reagent Pack and Calibrators***

The *Vitros* Immunodiagnostic Products Myoglobin Reagent Pack and *Vitros* Immunodiagnostic Products Myoglobin Calibrators are substantially equivalent to the DADE **Dimension** RxL Myoglobin (MYO) Method (predicate device) which was cleared by the FDA (K984191) for IVD use.

The relationship between the *Vitros* Myoglobin and the predicate device, determined by Passing & Bablok, is:

Vitros Myoglobin = 0.990 x X +0.81 (ng/mL),
with a correlation coefficient of 0.997,
where X is DADE **Dimension** RxL Myoglobin Method.

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* Myoglobin assay, (refer to the *Vitros* Myoglobin Reagent package insert for summaries of the results of these studies).

Table 1 lists the characteristics of the assays performed using the *Vitros* Myoglobin assay and the DADE **Dimension** RxL Myoglobin (MYO) assay.

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7. a. Comparison to predicate device: ***Reagent Pack and Calibrators,*** Continued

Table 1

Device Characteristic	New Device	Predicate Device
Calibration range	0-2000 ng/mL	0-1000 ng/mL
Basic principle	Solid phase immunoassay	Solid phase immunoassay
Tracer	Enzyme labeled	Enzyme labeled
Instrumentation	*Vitros* Immunodiagnostic System	DADE **Dimension** Immunoassay System
Antibody	Mouse monoclonal anti-myoglobin antibodies	Mouse monoclonal anti-myoglobin antibodies
Sample type	Serum and plasma (EDTA or heparin)	Serum and plasma (heparin)
Sample volume	10µL	20µL
Incubation time and temperature	8 minutes at 37°C	7 minutes at 37°C

7. b. Comparison to predicate device: ***Range Verifiers***

The *Vitros* Immunodiagnostic Products Myoglobin Range Verifiers are substantially equivalent to the *Vitros* Troponin I Range Verifiers (predicate device) which was cleared by the FDA (K992349) for IVD use.

Table 2 lists the similarities and differences of the device characteristics between the *Vitros* Myoglobin Range Verifiers with the predicate device, *Vitros* Troponin I Range Verifiers.

Table 2

Characteristics	New Device	Predicate Device
Intended Use	Assayed for use in verifying the calibration range of the *Vitros* Immunodiagnostic System when used for the measurement of Myoglobin. For *in vitro* use.	Assayed for use in verifying the calibration range of the *Vitros* Immunodiagnostic System when used for the measurement of cardiac Troponin I (cTnI). For *in vitro* use.
Matrix of Range Verifiers	A base matrix of freeze-dried horse serum spiked with analyte of human origin	A base matrix of freeze-dried human serum spiked with analyte of human origin.
Range Verifier Levels	Low and High	Low and High

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8. Conclusions

a. ***Reagent Pack and Calibrators:*** Equivalence was demonstrated using currently commercially available reagents along with patient samples by comparing the physical properties and intended uses of these devices with commercially available reagents.

b. ***Range Verifiers:*** Both the new device and the predicate device are intended for the assayed use in verifying the calibration range of immunoassays determined by immunoassay analyzers. The new device and predicate device are substantially equivalent.

The data presented in the premarket notification provide a reasonable assurance that the *Vitros* Myoglobin assay and the *Vitros* Myoglobin Range Verifiers are safe and effective for the stated intended uses and are substantially equivalent to the cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 5 2003

Ms. Charlotte Baker
Regulatory Affairs Associate
Ortho-Clinic Diagnostics, Inc.
Regulatory Affairs MC00881
100 Indigo Creek Drive
Rochester, NY 14626-5101

Re: k033300
Trade/Device Name: *Virtos* Immunodiagnostic Products Myoglobin Reagent Pack
Virtos Immunodiagnostic Products Myoglobin Calibrators
Virtos Immunodiagnostic Products Myoglobin Range Verifiers
Regulation Number: 21 CFR 866.5680
Regulation Name: Myoglobin immunological test system
Regulatory Class: Class II
Product Code: DDR; JIS; JJX
Dated: October 10, 2003
Received: October 14, 2003

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 (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

Indications for Use Statement

510(k) Number (if known): K033300

Device Name:

Vitros Immunodiagnostic Products Myoglobin Reagent Pack
Vitros Immunodiagnostic Products Myoglobin Calibrators
Vitros Immunodiagnostic Products Myoglobin Range Verifiers

Indications for Use:

For the *in vitro* quantitative measurement of myoglobin concentration in human serum or plasma (EDTA or heparin) to aid in the diagnosis of myocardial infarction.

For *in vitro* use in the calibration of the *Vitros* Immunodiagnostic System for the quantitative measurement of Myoglobin in human serum and plasma (EDTA or heparin).

Assayed for use in verifying the calibration range of the *Vitros* Immunodiagnostic System when used for the measurement of Myoglobin. For *in vitro* use.

(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)

Carol C Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033300