DEC - 9 2004

K042838

3.0 510(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: _____

3.1 Submitter name, address, contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
Phone: (585) 453-4253
Fax: (585) 453-3368

Contact Person: Darlene J. Phillips

3.2 Date of Preparation:

October 13, 2004

3.3 Device Proprietary Names:

Trade Names	VITROS Chemistry Products Calibrator Kit 23
	VITROS Chemistry Products PALB Performance Verifier I and II
Common Name	Prealbumin calibrator and controls

3.4 Classification Names

Classification Name: Calibrator (862.1150): Class II The Clinical Chemistry and Toxicology Panel of the FDA has placed calibrators in Class II.

Classification Name: Quality Control material (assayed and unassayed) (862.1660): Class I: The Clinical Chemistry and Toxicology Panel of the FDA has placed Quality Control material (assayed and unassayed) for clinical chemistry in Class I. Since this device is an assayed control, it meets the reserved criteria under Section 510(l) of the Food, Drug, and Cosmetic Act.

3.5 Predicate devices

The VITROS Chemistry Products Calibrator Kit 23 and VITROS Chemistry Products PALB Performance Verifiers are substantially equivalent to the VITROS Chemistry Products Calibrator Kit 17 and VITROS Chemistry Products hsCRP Performance Verifiers, respectively. The predicate devices were cleared by FDA (K041799) for IVD use.

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3.6 Device description

VITROS Chemistry Products Calibrator Kit 23

VITROS Chemistry Products Calibrator Kit 23 is a liquid ready use kit containing five levels for the calibration of VITROS 5,1 FS Chemistry Systems for the quantitative measurement of prealbumin.

These calibrators are prepared from processed human serum to which inorganic salts, buffers, and preservatives have been added.

VITROS Chemistry Products PALB Performance Verifiers I and II

VITROS Chemistry Products PALB Performance Verifiers contain two levels of liquid ready to use assayed controls for use in monitoring performance of PALB Reagents on VITROS 5,1 FS Chemistry Systems.

These controls are prepared from processed human serum to which inorganic salt, buffers and preservative have been added.

3.7 Device intended use

VITROS Chemistry Products Calibrator Kit 23

For *in vitro* diagnostic use only

VITROS Chemistry Products Calibrator Kit 23 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of prealbumin.

VITROS Chemistry Products PALB Performance Verifiers I and II

For *in vitro* diagnostic use only

VITROS Chemistry Products PALB Performance Verifiers are assayed controls used to monitor the performance of PALB Reagent on VITROS 5,1 FS Chemistry Systems.

3.8 Comparison to predicate device

The VITROS Chemistry Products Calibrator Kit 23 and VITROS Chemistry Products PALB Performance Verifiers are substantially equivalent to the VITROS Chemistry Products Calibrator Kit 17 and VITROS Chemistry Products hsCRP Performance Verifiers, respectively. The predicate devices were cleared by the FDA (K041799) for IVD use.

Tables 1 and 2 provide similarities and differences between the new devices and predicate devices.

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Table 1 **Table 1** lists the similarities and differences of the device characteristics between new device, VITROS Chemistry Products Calibrator Kit 23 and predicate device, VITROS Chemistry Products Calibrator Kit 17.

Device Characteristic	VITROS Calibrator Kit 23 New device	VITROS Calibrator Kit 17 Predicate device
Intended Use	For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 23 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of prealbumin (PALB).	For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 17 is used in conjunction with VITROS Chemistry Products FS Calibrator 1 to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of C-reactive protein (CRP) using VITROS hsCRP Reagent.
Fluid Matrix	A base matrix of processed human serum to which inorganic salts, buffers, and preservatives have been added.	A base matrix of stabilized human serum to which analytes and preservatives have been added
Analyte Levels	Five levels	Single level
Analyte	Prealbumin (transthyretin)	C-reactive protein
Traceability	CRM470	Same
Format	Liquid ready to use	Same

Table 2 **Table 2** lists the similarities and differences of the device characteristics between new device, VITROS PALB Performance Verifiers and predicate device, VITROS hsCRP Performance Verifiers.

Device Characteristic	VITROS PALB Performance Verifiers New device#2	VITROS hsCRP Performance Verifiers Predicate device#2
Intended Use	For *in vitro* diagnostic use only. VITROS Chemistry Products PALB Performance Verifiers are assayed controls used to monitor the performance of PALB Reagent on VITROS 5,1 FS Chemistry Systems.	For *in vitro* diagnostic use only. VITROS Chemistry Products hsCRP Performance Verifiers are assayed controls used to monitor performance of hsCRP Reagent on VITROS 5,1 FS Chemistry Systems.
Fluid Matrix	A base matrix of processed human serum to which inorganic salt, buffers and preservative have been added.	A base matrix of human plasma and plasma proteins to which stabilizers and preservative have been added.
Analyte Levels	Low and High	Low, Medium and High
Analyte	Prealbumin (transthyretin)	C-reactive protein
Format	Liquid ready to use	Same

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 9 2004

Ms. Darlene J. Phillips, RAC
Regulatory Affairs Associate
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626

Re: k042838
Trade/Device Name: VITROS Chemistry Products Calibrator Kit 23
VITROS Chemistry Products PALB Performance Verifiers I and II
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT, JJX
Dated: October 13, 2004
Received: October 14, 2004

Dear Ms. Phillips:

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,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

1.0 Indications for Use

510(k) Number (if known): K042838

Device Name: VITROS Chemistry Products Calibrator Kit 23
VITROS Chemistry Products PALB Performance Verifiers I and II

Indications for Use: For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 23 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of prealbumin.

For *in vitro* diagnostic use only. VITROS Chemistry Products PALB Performance Verifiers are assayed controls used to monitor the performance of PALB Reagent on VITROS 5,1 FS Chemistry Systems.

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042838