NOV 18 2004

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: K042643

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:

September 24, 2004

3.3 Device Proprietary Names:

Trade Names: VITROS Chemistry Products mALB Reagent
VITROS Chemistry Products Calibrator Kit 24
VITROS Chemistry Products mALB Performance Verifiers I and II

Common Name: Microalbumin assay

3.4 Classification Names

Classification Name: Albumin immunological test system (866.5040): Class: II (Special controls)

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.

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3.5 Predicate device

3.5.1 The VITROS Chemistry Products mALB Reagent and VITROS Chemistry Products Calibrator Kit 24 are substantially equivalent to the N Antiserum to Human Albumin assayed on the Dade Behring BN System.

3.5.2 The VITROS Chemistry Products mALB Performance Verifiers I and II are substantially equivalent to the VITROS Chemistry Products Performance Verifiers I and II.

3.6 Device description

The VITROS 5,1 FS Chemistry System is a fully automated clinical chemistry analyzer intended for use in the *in vitro* determination of various analytes in human specimens (serum, plasma, urine, and cerebrospinal fluid). The VITROS 5,1 FS System is designed for use with VITROS Chemistry Products MicroTip and Thin Film assays.

The system is comprised of four main elements:

1 The VITROS 5,1 FS Chemistry System – instrumentation, which provides automated use of the chemistry reagents. The VITROS 5,1 FS Chemistry System was cleared for market by a separate 510(k) premarket notification (K031924).

2 The VITROS Chemistry Products MicroTip range of liquid reagent products (in this case VITROS Chemistry Products mALB Reagent, VITROS Chemistry Products Calibrator Kit 24 and VITROS Chemistry Products mALB Performance Verifiers I and II), which are combined by the VITROS 5,1 FS Chemistry System to perform the VITROS mALB assay.

3 The VITROS Chemistry Products Thin Film range of dry products, which are dry, multilayered, analytical elements, coated on polyester supports. The thin film products each have their own 510(k) clearance numbers and were cleared for market for use on the VITROS 5,1 FS Chemistry System through submission of information required by the ODE Guidance Document: "Data For Commercialization Of Original Equipment Manufacturer, Secondary and Generic Reagents For Automated Analyzers". The required information was provided in the VITROS 5,1 FS Chemistry System premarket notification (K031924).

4. Common reagents used by multiple assays on the VITROS System (in this case, VITROS Chemistry Products FS Diluent Pack 2).

The VITROS System and reagents are designed specifically for use with the VITROS Chemistry Products range of products.

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3.7 Device intended use

3.7.1 VITROS Chemistry Products mALB Reagent

For *in vitro* diagnostic use only. VITROS Chemistry Products mALB Reagent is used to quantitatively measure albumin concentration in human urine (mALB).

3.7.2 VITROS Chemistry Products Calibrator Kit 24

For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 24 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of albumin.

3.7.3 VITROS Chemistry Products mALB Performance Verifiers I and II

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

3.8 Comparison to predicate device

3.8.1 The VITROS Chemistry Products mALB Reagent and VITROS Chemistry Products Calibrator Kit 24 are substantially equivalent to the N Antiserum to Human Albumin assay on the Dade Behring BN ProSpec System (predicate device) which was cleared by the FDA (K972929) for IVD use.

The relationship between the VITROS mALB assay and the predicate device, determined by the Passing & Bablock[1] linear regression is:

VITROS mALB assay = 0.93x + 0.03

with a correlation coefficient of 0.977,

where X is the result for the N Antiserum to Human Albumin assay on the Dade Behring BN ProSpec System.

In addition to the above mentioned correlation study, studies were performed to determine the precision, analytical sensitivity, specificity and expected values of the VITROS mALB assay, (refer to VITROS mALB Reagent Instructions For Use in Section 8 for summaries of the results of these studies).

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Table 1 Table 1 lists the characteristics of the VITROS mALB assay (new device) and the Dade N Antiserum to Human Albumin assay (predicate device).

Device Characteristic	VITROS mALB assay (New Device)	Dade Albumin assay (Predicate Device)
Intended Use	For *in vitro* diagnostic use only. VITROS Chemistry Products mALB Reagent is used to quantitatively measure albumin concentration in human urine (mALB).	In vitro diagnostic reagents for the quantitative determination of albumin in human urine using the BN Systems.
Method	Immunoturbidimetry	Rate nephelometry
Reportable Range	0.6 to 19.0 mg/dL	0.0 to 34.0 mg/dL
Instrumentation	VITROS 5,1 FS Chemistry Systems	Dade Behring BN ProSpec Systems
Sample type	Urine	Urine
Reactive Ingredient	Goat anti-sera to human albumin	Rabbit antiserum to human albumin

3.8.2 The VITROS Chemistry Products mALB Performance Verifiers I and II are substantially equivalent to the VITROS Chemistry Products Performance Verifiers (predicate device) which were cleared by the FDA (K041720) for IVD use.

Table 2 Table 2 lists the similarities and differences of the device characteristics between the VITROS mALB Performance Verifiers with the predicate device, VITROS Performance Verifiers I and II.

Device Characteristic	New device	Predicate device
Intended Use	For *in vitro* diagnostic use only. VITROS Chemistry Products mALB Performance Verifiers are assayed controls used to monitor the performance of mALB Reagents on VITROS 5,1 FS Chemistry Systems.	For *in vitro* diagnostic use only. VITROS Performance Verifier is an assayed control used to monitor performance on VITROS Chemistry Systems.
Fluid Matrix	A base matrix of processed human serum to which inorganic salt, buffers, protein, surfactant and preservative have been added.	A base matrix of freeze-dried human serum to which enzymes, electrolytes, stabilizers, preservatives and other organic analytes have been added.
Analyte Levels	Low and High	Low and High

3.9 Conclusions

The data presented in the premarket notification provide a reasonable assurance that the VITROS mALB assay and the VITROS Chemistry Products mALB Performance Verifiers are safe and effective for the stated intended uses and are substantially equivalent to the cleared predicate devices.

Equivalence to the predicates was demonstrated using commercially available reagents along with patient samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 18 2004

Ms. Darlene J. Phillips, RAC
Regulatory Affairs Associate
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626-5101

Re: k042643
Trade/Device Name: VITROS Chemistry Products mALB Reagent
VITROS Chemistry Products Calibrator Kit 24
VITROS Chemistry Products mALB Performance Verifiers I and II
Regulation Number: 21 CFR 866.5040
Regulation Name: Albumin immunological test system
Regulatory Class: Class II
Product Code: DCF, JJX, JIT
Dated: September 24, 2004
Received: September 27, 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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
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): K042643

Device Name:
VITROS Chemistry Products mALB Reagent
VITROS Chemistry Products Calibrator Kit 24
VITROS Chemistry Products mALB Performance Verifiers I and II

Indications for Use:

For *in vitro* diagnostic use only.
VITROS Chemistry Products mALB Reagent is used to quantitatively measure albumin concentration in human urine (mALB). Measurement of urinary albumin aids in the diagnosis of diabetic nephropathy, hypertension and cardiovascular disease.

For *in vitro* diagnostic use.
VITROS Chemistry Products Calibrator Kit 24 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of albumin in urine (mALB).

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

Prescription Use ✓ 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) K042643