SEP - 9 2004

1.0 510(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: K041764

1.1 Submitter name, address, contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
Phone: (585) 453-3482
Fax: (585) 453-3368

Contact Person: Carey A. Mayo, M.S., RAC

1.2 Date of Preparation: June 29, 2004

1.3 Device Proprietary Name(s)

Trade Name(s) VITROS Chemistry Products %A1c Reagent Kit
VITROS Chemistry Products Hemolyzing Reagent
VITROS Chemistry Products Calibrator Kit 18
VITROS Chemistry Products FS Calibrator 1
VITROS Chemistry Products %A1c Performance Verifiers I and II

Common Name Glycohemoglobin assay and controls

1.4 Classification Name(s)

Glycosylated hemoglobin assay: Class II (21 CFR 864.7470)
Assayed Controls: Class I, reserved (21 CFR 862.1660)

1.5 Predicate device

The VITROS Chemistry Products %A1c Assay is substantially equivalent to the A1c 2.2 Plus Glycohemoglobin Assay (Tosoh Medics, Inc.).

The VITROS Chemistry Products %A1c Performance Verifiers are substantially equivalent to the VITROS Chemistry Products Performance Verifiers.

1.6 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 Chemistry 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 range of MicroTip assays, in this case the VITROS Chemistry Products %A1c Reagent Kit, VITROS Chemistry Products Hemolyzing Reagent, VITROS Chemistry Products Calibrator Kit 18, VITROS Chemistry Products FS Calibrator 1, and the VITROS Chemistry Products %A1c Performance Verifiers, which are combined by the VITROS 5,1 FS Chemistry System to perform the VITROS %A1c assay.

3. The VITROS Chemistry Products Thin Film range of products, which are dry, multilayered, analytical elements, coated on polyester supports. The thin film products each have there 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 and VITROS Chemistry Products FS Reconstitution Diluent).

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

1.7 Device intended use

VITROS Chemistry Products %A1c Reagent Kit: For *in vitro* diagnostic use only. VITROS Chemistry Products %A1c Reagent Kit is used to calculate percent glycated hemoglobin (%A1c) in pretreated human whole blood by quantitative measurement of hemoglobin (Hb) and hemoglobin A1c (HbA1c). Measurements of percentage A1c are effective in monitoring long-term glucose control in individuals with diabetes mellitus.

VITROS Chemistry Products Calibrator Kit 18: For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 18 is used in conjunction with VITROS Chemistry Products FS Calibrator 1 to calibrate VITROS 5,1 FS Chemistry Systems for the calculation of percent glycated hemoglobin (%A1c).

VITROS Chemistry Products %A1c Performance Verifier I and II: For *in vitro* diagnostic use only. VITROS Chemistry Products %A1c Performance Verifiers are assayed controls used to monitor performance of %A1c Reagent Kit on VITROS 5,1 FS Chemistry Systems.

1.8 Comparison to predicate device: Reagent Kit and Calibrators

The VITROS Chemistry Products %A1c Reagent Kit, VITROS Chemistry Products Calibrator Kit 18 and VITROS Chemistry Products FS Calibrator 1 are substantially equivalent to the A1c 2.2 Plus Glycohemoglobin Assay (Tosoh Medics, Inc.), which was cleared by FDA (K972265) for IVD use.

The relationship between the VITROS %A1c assay and the predicate device in NGSP units, determined by least squares linear regression, is:

VITROS %A1c assay = 1.0374 X – 0.3426 %A1c
with a correlation coefficient of 0.9872,
where X is the Tosoh A1c 2.2 Plus Glycohemoglobin Assay on the TOSOH Automated Glycohemoglobin Analyzer.

In addition to the above mentioned correlation study, studies were performed to determine the precision, expected values, linearity, and specificity of the VITROS %A1c assay, (refer to the VITROS Chemistry Products %A1c Reagent Kit Instructions for Use for summaries of the results of these studies).

The table below lists the characteristics of the VITROS %A1c Assay and the A1c 2.2 Plus Glycohemoglobin Assay (Tosoh Medics, Inc.).

Device Characteristic	VITROS %A1c Assay (New device)	A1c 2.2 Plus Glycohemoglobin Assay (Predicate device)
Intended Use	To determine %A1c in whole blood	To determine %A1c in whole blood
Standardization	Traceable to both the Diabetes Control and Complications Trial (DCCT) and IFCC reference methods. Certified by the National Glycohemoglobin Standardization Program (NGSP).	Traceable to both the Diabetes Control and Complications Trial (DCCT) and IFCC reference methods. Certified by the National Glycohemoglobin Standardization Program (NGSP).
Basic principle	Turbidimetric inhibition immunoassay	High performance liquid chromatography (HPLC)
Reportable Range	4 – 14 %A1c NGSP	4 – 19 %A1c NGSP
Reagents	Liquid ready to use	Non-porous cation exchange column
Instrumentation	VITROS 5,1 FS Chemistry System	A1c 2.2 Plus Automated Glycohemoglobin Analyzer (Tosoh Medics, Inc.)
Sample type	Whole blood (EDTA, heparin, sodium fluoride/potassium oxalate)	Whole blood (undiluted or diluted)

1.9 Comparison to predicate device: Performance Verifiers

VITROS Chemistry Products %A1c Performance Verifiers are substantially equivalent to VITROS Chemistry Products Performance Verifiers (predicate device) which were cleared by the FDA (K904768) for IVD use.

The table below lists the characteristics of the VITROS Chemistry Products %A1c Performance Verifiers and the VITROS Chemistry Products Performance Verifiers.

Device Characteristic	VITROS %A1c Performance Verifiers (New device)	VITROS Performance Verifiers (Predicate device)
Intended Use	VITROS %A1c Performance Verifier is an assayed control used to monitor performance of %A1c Reagent Kit on VITROS 5,1 FS Chemistry Systems.	VITROS Performance Verifier is an assayed control used to monitor performance on VITROS Chemistry Systems.
Matrix	A base matrix of freeze-dried hemolysate derived from human and ovine blood to which surfactants, stabilizer, and preservatives have been added.	A base matrix of freeze-dried human serum to which enzymes, electrolytes, stabilizers, preservatives and other organic analytes have been added.
Levels	Low and High	Low and High

1.10 Conclusions

The data presented in the premarket notification provide a reasonable assurance that the VITROS Chemistry Products %A1c assay and the VITROS %A1c 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 a commercially available assay along with patient samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 9 2004

Carey A. Mayo, M.S., RAC
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Ortho-Clinical Diagnostics
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Rochester, NY 14626

Re: k041764
Trade/Device Name: VITROS Chemistry Products %A1c Reagent Kit
VITROS Chemistry Products Calibrator Kit 18
VITROS Chemistry Products FS Calibrator 1
VITROS Chemistry Products %A1c Performance Verifiers I and II
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated Hemoglobin assay
Regulatory Class: Class II
Product Code: LCP, JIT, JJX
Dated: June 29, 2004
Received: June 30, 2004

Dear Ms. Mayo:

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

2.0 Indications for Use Statement

510(k) Number (if known): K041764

Device Name:

1. VITROS Chemistry Products %A1c Reagent Kit
2. VITROS Chemistry Products Calibrator Kit 18
3. VITROS Chemistry Products FS Calibrator 1
4. VITROS Chemistry Products %A1c Performance Verifiers I and II

Indications for Use:

1. For *in vitro* diagnostic use only. VITROS Chemistry Products %A1c Reagent Kit is used to calculate percent glycated hemoglobin (%A1c) in pretreated human whole blood by quantitative measurement of hemoglobin (Hb) and hemoglobin A1c (HbA1c). Measurements of percentage A1c are effective in monitoring long-term glucose control in individuals with diabetes mellitus.
2. & 3. For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 18 is used in conjunction with VITROS Chemistry Products FS Calibrator 1 to calibrate VITROS 5,1 FS Chemistry Systems for the calculation of percent glycated hemoglobin (%A1c).
4. For *in vitro* diagnostic use only. VITROS Chemistry Products %A1c Performance Verifiers are assayed controls used to monitor performance of %A1c Reagent Kit 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 C. Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K041764