

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: K091861

SEP - 3 2009

- 1. Submitter name, address, contact** Ortho-Clinical Diagnostics, Inc.
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Contact Person: Marlene A. Hanna
- 2. Preparation date** Date Special 510(k) prepared: June 18, 2009
- 3. Device name** Trade or Proprietary Name:
VITROS Chemistry Products Na⁺ DT Slides
Common Name: sodium test
Classification Name: sodium test system (21 CFR 862.1665)

VITROS Chemistry Products DT Calibrator Kit
Common Name: calibrator
Classification Name: Calibrator (21 CFR 862.1150)
- 4. Predicate device** The VITROS Chemistry Products Na⁺ DT Slides (modified) and VITROS Chemistry Products DT Calibrator Kit are substantially equivalent to the VITROS Chemistry Products Na⁺ Slides (k081411, cleared on June 30, 2008) and VITROS Chemistry Products DT Calibrator Kit (k083680, cleared February 26, 2009).

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5. Device Description

The VITROS Chemistry Products Na⁺ DT Slide assay is performed using the VITROS Chemistry Products Na⁺ DT Slide and the VITROS Chemistry Products DT Calibrator Kit on the VITROS DT60/DT60 II Chemistry Systems. The VITROS Na⁺ DT Slide is a multilayered, analytical element coated on a polyester support that uses direct potentiometry¹ for measurement of sodium ions. All reactions necessary for a single quantitative measurement of sodium take place within the multi-layered analytical element of a VITROS Chemistry Products Na⁺ DT Slide. The slide consists of two ion-selective electrodes, each containing methyl monensin (an ionophore for sodium), a reference layer, and a silver layer and a silver chloride layer coated on a polyester support.

VITROS Chemistry Products Na⁺ DT Slides use ion-selective electrodes for potentiometric measurements of ionic sodium. Ionic sodium determinations are made by simultaneously depositing 10 uL each of a reference fluid and a sample fluid on separate halves of the VITROS Chemistry Products Na⁺ DT Slide. The electrode receiving the reference fluid is identified as the reference electrode. A paper bridge connects the reference electrode and the indicator electrode, which receives the sample fluid. A stable liquid junction between the two fluids is formed in the paper bridge. The sodium ions in the tested reference and sample fluids migrate to the silver/ silver chloride layers and establishes equilibrium.

After an incubation period, the electrometer in the VITROS Chemistry System measures the potential difference between the reference and indicator electrodes. Each electrode responds to the activity of sodium ions in the respective fluids to produce a potential for the concentration cell. The VITROS DT60/DT60II Chemistry System's microprocessor uses this measurement and the stored calibration parameters to determine the concentration value of the sodium ion in the sample fluid. The test result is reported in millimoles per liter (mmol/ L).

VITROS Chemistry Products DT Calibrator Kit contains four levels of lyophilized standards with corresponding diluents. The standards are prepared from bovine serum albumin and processed bovine serum to which enzymes, electrolytes, stabilizers, preservatives and other organic analytes have been added. The companion diluents are prepared from processed water to which inorganic salts have been added.

The VITROS DT60/ DT60 II Chemistry System and reagents are designed specifically for use with the VITROS Chemistry Products range of products.

**6. Device
intended
use**

VITROS Chemistry Products Na⁺ DT Slides

For *in vitro* diagnostic use only. VITROS Na⁺ DT Slides quantitatively measure sodium (Na⁺) concentration in serum and plasma.

VITROS Chemistry Products DT Calibrator Kit

For *in vitro* diagnostic use only. VITROS Chemistry Products DT Calibrator Kit is specially formulated for use as calibrators for the quantitative measurement of ALB, ALKP, ALT, AMYL, AST, TBIL, NBIL, BUN/UREA, Ca, CHOL, CK, Cl⁻, Co₂, CREA, CRSC, Fe, GGT, GLU, HDLC, K⁺, LAC, LDH, LIPA, Mg, Na⁺, NH₃, PHOS, TP, TRIG, urCR, and URIC on VITROS DT Chemistry Systems.

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7. **Comparison to predicate device** The VITROS Chemistry Products Na⁺ DT Slide (modified) and VITROS Chemistry Products DT Calibrator Kit are substantially equivalent to VITROS Chemistry Products Na⁺ Slide and VITROS Chemistry Products DT Calibrator Kit, which were Cleared by the FDA for *in vitro* diagnostic use.

VITROS Chemistry Products Na⁺ Slide: (K081411, cleared June 30, 2008)

VITROS Chemistry Products DT Calibrator Kit: (K083680, cleared February 26, 2009).

Table 1 lists the characteristics of the tests performed using the VITROS Na⁺ DT Slide (modified) and the VITROS Na⁺ DT Slide (current).

Table 1. List of VITROS Chemistry Products Na⁺ DT Slide Characteristics: Comparison to Predicate Device

Device Characteristic	New Device VITROS Chemistry Products Na ⁺ DT Slide (Modified)	Predicate Device VITROS Chemistry Products Na ⁺ Slide (Current)
Intended Use	No Change.	For <i>in vitro</i> diagnostic use only. VITROS Na ⁺ DT Slides quantitatively measure sodium (Na ⁺) concentration in serum and plasma.
Fundamental scientific technology	No Change.	Dry, multilayered slide utilizing direct potentiometry
Reactive Ingredients per cm ²	No Change.	Silver 0.4 mg; silver chloride 0.2 mg; sodium chloride 0.3 mg; and methyl monensin 50 µg.
Sample type	No Change.	Serum, plasma
Instrumentation	VITROS 250/350/950 and 5,1 FS Chemistry Systems and the VITROS 5600 Integrated System	VITROS DT60 and DT60II Chemistry Systems
Manufacturing Process of the ISE baseweb* (Ag/AgCl and Support Layers of the Na ⁺ DT Slide)	Same	Magnetic sputter deposition
Composition of ISE baseweb component	Same	Ag/AgCl concentration: Silver 0.4 mg and silver chloride 0.2 mg Nickel Stripes: NiCr (80% Nickel, 20% Chromium).

*ISE (Ion-Selective Electrode) baseweb= Polyethylene terephthalate film (substrate used for metallized film) coated with silver (Ag)/ silver chloride (Ag/Cl) and striped with nominal nickel (Ni) stripes. The "ISE baseweb" refers to the Ag/ AgCl with nickel stripes layer and support layer of the VITROS Chemistry Products Na⁺ DT Slide.

NOTE: No modifications were made to VITROS Chemistry Products DT Calibrator Kit.

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8. Conclusions

The information presented in the premarket notification demonstrates that the performance of the VITROS Chemistry Products Na⁺ DT Slides (modified) for use with human serum and plasma is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using manufactured slides along with patient and quality control samples with measured sodium values spanning the assay range.

The information presented in the premarket notification provides a reasonable assurance that the VITROS Chemistry Products Na⁺ DT Slides (modified) for use with human serum and plasma is safe and effective for the stated intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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Rochester, NY 14626-5101

SEP - 8 2009

Re: k091861
Trade/Device Name: VITROS Chemistry Products Na+ DT Slides
Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium Test System
Regulatory Class: Class II
Product Code: JGS, JIX
Dated: June 18, 2009
Received: June 19, 2009

Dear Ms. Hanna:

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).

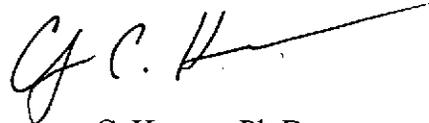
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

K091861

1. Device Name: VITROS Chemistry Products Na⁺ DT Slides

Indication For Use: For *in vitro* diagnostic use only. VITROS Na⁺ DT Slides quantitatively measure sodium (Na⁺) concentration in serum and plasma. Measurements used by this device are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic hormone secretion, or other disease involving electrolyte imbalance.

2. Device Name: VITROS Chemistry Products DT Calibrator Kit

VITROS Chemistry Products DT Calibrator Kit is specially formulated for use as calibrators for the quantitative measurement of ALB, ALKP, ALT, AMYL, AST, TBIL, NBIL, BUN/UREA, Ca, CHOL, CK, Cl⁻, Co₂, CREA, CRSC, Fe, GGT, GLU, HDLC, K⁺, LAC, LDH, LIPA, Mg, Na⁺, NH₃, PHOS, TP, TRIG, urCR, and URIC on VITROS DT Chemistry Systems. For *in vitro* diagnostic use only.

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use
(21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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