JUN 30 2008

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: K081411

1.	**Submitter name, address, contact**	Ortho-Clinical Diagnostics, Inc. 100 Indigo Creek Drive Rochester, New York 14626-5101 (585) 453-4041 Contact Person: Marlene A. Hanna
2.	**Preparation date**	Date Special 510(k) prepared: May 19, 2008
3.	**Device name**	Trade or Proprietary Name: VITROS Chemistry Products Na^+ Slides Common Name: Sodium test Classification Name: Sodium test system (21 CFR 862.1665) VITROS Chemistry Products Calibrator Kit 2 Common Name: calibrator Classification Name: Calibrator (21 CFR 862.1150)
4.	**Predicate device**	The VITROS Chemistry Products Na^+ Slides (modified) and VITROS Chemistry Products Calibrator Kit 2 are substantially equivalent to the VITROS Chemistry Products Na^+ Slides (current slide) and VITROS Chemistry Products Calibrator Kit 2. The FDA cleared the VITROS Chemistry Products Na^+ Slides on May 7, 1996 (K961099) under the product name EKTACHEM Clinical Chemistry Slide Sodium (Na^+). With the purchase of KODAK Clinical Products Division by Johnson and Johnson, the product branding was later revised to VITROS Chemistry Products Na^+ Slides. The most recent FDA clearance for the VITROS Chemistry Products Calibrator Kit 2 was December 7, 2007 (K073157).

5. Device Description

The VITROS Na^+ assay is performed using the VITROS Chemistry Products Na^+ Slide and the VITROS Chemistry Products Calibrator Kit 2 on the VITROS Chemistry Systems. The VITROS Na^+ Slide is a multilayered, analytical element coated on a polyester support that uses direct potentiometry for measurement of ionic sodium. All reactions necessary for a single quantitative measurement of sodium take place within the multi-layered analytical element of a VITROS Chemistry Products Na^+ 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^+ 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^+ 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 in approximately 20 seconds. The sodium ions in the tested reference and sample fluids migrate to the silver/ silver chloride layers and establish equilibrium.

After a two-minute 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 Chemistry System's microcomputer 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 Calibrator Kit 2 contains four levels of lyophilized standards with corresponding diluents. The standards are prepared from processed bovine serum to which bovine cholesterol, chicken egg yolk, inorganic salts, electrolytes, buffers, stabilizers, and preservatives have been added. The companion diluents are prepared from processed water to which inorganic salts have been added. In addition, Calibrator 4 Diluent contains 0.5 M diethylaminoethanol and 0.01 M (ethylenedinitrilo) tetraacetic acid.

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

6. Device intended use

VITROS Chemistry Products Na^+ Slides
For *in vitro* diagnostic use only. VITROS Na^+ Slides quantitatively measure sodium (Na^+) concentration in serum, plasma, and urine.

VITROS Chemistry Products Calibrator Kit 2
For *in vitro* diagnostic use only. VITROS Calibrator Kit 2 is used to calibrate the VITROS Chemistry Systems for the quantitative measurement of CHOL, Cl^-, ECO2, HDLC, K^+, Na^+, and TRIG.

7. Comparison to predicate device

The VITROS Chemistry Products Na^+ Slide (modified) and VITROS Chemistry Products Calibrator Kit 2 are substantially equivalent to VITROS Chemistry Products Na^+ Slide and VITROS Chemistry Products Calibrator Kit 2, which were Cleared by the FDA for *in vitro* diagnostic use.

VITROS Chemistry Products Na^+ Slide: (K961099, cleared May 7, 1996)
VITROS Chemistry Products Calibrator Kit 2: (K073157, cleared December 7, 2008).

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

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

Device Characteristic	New Device VITROS Chemistry Products Na^+ Slide (Modified)	Predicate Device VITROS Chemistry Products Na^+ Slide (Current)
Intended Use	No Change.	For *in vitro* diagnostic use only. VITROS Na^+ Slides quantitatively measure sodium (Na^+) concentration in serum, plasma, and urine.
Fundamental scientific technology	No Change.	Dry, multilayered slide utilizing direct potentiometry
Sample type	No Change.	Serum, plasma, urine
Instrumentation	VITROS 250, 950 and 5,1FS Series Analyzers. The 550 and 750 analyzers will not be supported by OCD as of January 1, 2008.	VITROS 250, 550, 750, 950 and 5,1FS Series Analyzers
Reactive Ingredients per cm^2	No Change.	Silver 0.4 mg and silver chloride 0.2 mg; sodium chloride 0.3 mg, methyl monensin 50 µg.
Other Ingredients	Binders, buffer, plasticizers, stabilizer, surfactants and nickel-chromium.	Binders, buffer, plasticizers, stabilizer, surfactants and nickel.
Composition of ISE baseweb* component	Ag/AgCl concentration: No change Nickel Stripes: NiCr (80% Nickel, 20% Chromium)	Ag/AgCl concentration: Silver 0.4 mg and silver chloride 0.2 mg Nickel Stripes: Ni (99+% Nickel)
Manufacturing Process of the ISE baseweb* (Ag/AgCl and Support Layers of the Na^+ Slide)	Magnetic sputter deposition	Electron beam evaporation

* 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^+ Slide.

NOTE: No modifications were made to VITROS Chemistry Products Calibrator Kit 2. VITROS Calibrator Kit 2 is included in this submission, since the VITROS Na+ Slide is used in conjunction with VITROS Calibrator Kit 2, and together is considered to be to the "VITROS Na+ assay".

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8. Conclusions

The information presented in the premarket notification demonstrates that the performance of the VITROS Chemistry Products Na^+ Slides (modified) for use with human serum, plasma, and urine 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^+ Slides (modified) for use with human serum, plasma, and urine is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ortho-Clinical Diagnostics, Inc.
c/o Ms. Marlene A. Hanna
Regulatory Affairs Manager
100 Indigo Creek Drive
Rochester, NY 14626-4041

JUN 30 2008

Re: k081411
Trade Name: VITROS Chemistry Products Na+ Slides, VITROS Chemistry Products Calibrator Kit 2
Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium Test System
Regulatory Class: Class II
Product Codes: JGS, JJX
Dated: May 19, 2008
Received: May 20, 2008

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.

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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., 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

Indication for Use

510(k) Number (if known):

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

Indication For Use: For *in vitro* diagnostic use only. VITROS Na^+ Slides quantitatively measure sodium (Na^+) concentration in serum, plasma, and urine. 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 Calibrator Kit 2

Indication For Use: For *in vitro* diagnostic use only. VITROS Calibrator Kit 2 is used to calibrate the VITROS Chemistry Systems for the quantitative measurement of CHOL, Cl^-, ECO2, HDLC, K^+, Na^+, and TRIG.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

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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