Ortho-Clinical Diagnostics
a Johnson & Johnson company

100 Indigo Creek Drive
Rochester, New York 14626-5101

DEC 15 2006

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: K063591

1. **Submitter name, address, contact**

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Contact Person: Michael M. Byrne

2. **Preparation date**

November 29, 2006

3. **Device name**

Trade or Proprietary Name:
VITROS Chemistry Products CREA Slides
VITROS Chemistry Products Calibrator Kit 1

Common Name: CREA test
Classification Name: Creatinine test system (21 CFR 862.1225).

Common Name: Calibrator Kit 1
Classification Name: Calibrator (21 CFR 862.1150)

4. **Predicate device**

The VITROS CREA assay (modified device) is substantially equivalent to the VITROS CREA assay (original). This assay was originally cleared under the VITROS Chemistry Products CREA Slides and VITROS Chemistry Products Calibrator Kit 1 Premarket Notification K001310.

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5. Device description

The VITROS CREA assay is performed using the VITROS Chemistry Products CREA Slides, and the VITROS Chemistry Products Calibrator Kit 1 on VITROS Chemistry Systems.

The VITROS CREA Slide is a multilayered, analytical element coated on a polyester support.

A drop of patient sample is deposited on the slide and is evenly distributed by the spreading layer to the underlying layers. Creatinine diffuses to the reagent layer, where it is hydrolyzed to creatine in the rate-determining step. The creatine is converted to sarcosine and urea by creatine amidinohydrolase. The sarcosine, in the presence of sarcosine oxidase, is oxidized to glycine, formaldehyde, and hydrogen peroxide. The final reaction involves the peroxidase-catalyzed oxidation of a leuco dye to produce a colored product.

Following addition of the sample, the slide is incubated. During the initial reaction phase, endogenous creatine in the sample is oxidized. The resulting change in reflection density is measured at 2 time points.

Once a calibration has been performed for each slide lot, creatinine concentration in unknown samples can be determined using the software-resident two-point rate math model and the change in reflectance calculated for each unknown test slide.

VITROS Calibrator Kit 1 contains three levels of lyophilized standards with corresponding diluents. The standards are prepared from processed bovine serum to which organic analytes, electrolytes, stabilizers, and preservatives have been added. The diluents are prepared from processed water to which inorganic salts have been added. Once reconstituted, the standards are used to calibrate VITROS Chemistry Systems for the quantitative measurement of creatinine in serum, plasma and urine.

Calibration of the VITROS CREA assay requires the use of all three of the calibrator levels (bottles 1, 2 and 3).

6. Device intended use

For *in vitro* diagnostic use only.

VITROS CREA Slides quantitatively measure creatinine (CREA) concentration in serum, plasma, and urine.

For *in vitro* diagnostic use only.

VITROS Calibrator Kit 1 is used to calibrate VITROS Chemistry Systems for the quantitative measurement of BUN/UREA, Ca, CREA, GLU, LAC, Li, Mg, PHOS, SALI, THEO, and URIC.

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7. Comparison to predicate device The VITROS CREA assay (modified device) is substantially equivalent to the predicate, VITROS CREA assay (original), which was cleared by the FDA (K001310)) for *in vitro* diagnostic use.

Table 1 List of Assay Characteristics: Comparison to Predicate Device

Device Characteristic	Modified Device VITROS CREA assay (modified)	Predicate Device VITROS CREA assay (original)
Intended Use	No change	For *in vitro* diagnostic use only. VITROS CREA Slides quantitatively measure creatinine (CREA) concentration in serum, plasma, and urine. For *in vitro* diagnostic use only. VITROS Calibrator Kit 1 is used to calibrate VITROS Chemistry Systems for the quantitative measurement of BUN/UREA, Ca, CREA, GLU, LAC, Li, Mg, PHOS, SALI, THEO, and URIC.
Calibration traceability	The values assigned to the VITROS Chemistry Products Calibrator Kit 1 for Creatinine are traceable to a Gas Chromatography Isotope Dilution Mass Spectrometry (GC/IDMS) method[1] and NIST SRM®914, creatinine standard reference material.	Traceable to Certified NIST (National Institute of Standards and Technology) Reference Material SRM® (Standard Reference Material) 914a.
Reference Interval (Serum)	Males: 0.7 – 1.3 mg/dL Females: 0.6 – 1.0 mg/dL	0.8 –1.5 mg/dL 0.7 –1.2 mg/dL
Reference Interval (Urine, 24 hour)	Males: 1000 - 2000 mg/day[2] Females: 800 - 1800 mg/day[2]	800 – 2800 mg/day (Male and Female)
Reportable range Serum Urine	 No Change 1.2 – 346.5 mg/dL (after multiplying by a dilution factor of 21)	 0.05 – 14.0 mg/dL 1.05 – 346.5 mg/dL (after multiplying by a dilution factor of 21)
Sample type	No change	Serum, Plasma, Urine
Basic principle	No change	Two point colorimetric rate
Instrumentation	No change	VITROS Chemistry Systems

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8. Conclusions The information presented in the pre-market notification demonstrates that the performance of the VITROS CREA assay (modified device) for use with human serum, plasma and urine is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using manufactured reagents along with quality control fluids, proficiency samples and human serum, plasma, and urine samples with measured creatinine values spanning the assay range.

The information presented in the premarket notification provides a reasonable assurance that the VITROS CREA assay (modified device) 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

Mr. Michael M. Byrne
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DEC 15 2006

Re: k063591
Trade/Device Name: VITROS Chemistry Products CREA Slides and VITROS Chemistry Products Calibrator Kit 1
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: Class II
Product Code: JFY, JIX
Dated: November 30, 2006
Received: December 1, 2006

Dear Mr. Byrne:

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)276-0484. 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/industry/support/index.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

Indications for Use

510(k) Number (if known): K063591

Device Name: VITROS Chemistry Products CREA Slides
VITROS Chemistry Products Calibrator Kit 1

Indications for Use: For *in vitro* diagnostic use only.
VITROS CREA Slides quantitatively measure creatinine (CREA) concentration in serum, plasma, and urine.

A creatinine test system is a device intended to measure creatinine levels in plasma and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

For *in vitro* diagnostic use only.
VITROS Calibrator Kit 1 is used to calibrate VITROS Chemistry Systems for the quantitative measurement of BUN/UREA, Ca, CREA, GLU, LAC, LI, Mg, PHOS, SALI, THEO, and URIC.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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