

K073634

JUN 19 2008

## 510(k) Summary

<b>Submitter's Name/Address</b>	<b>Contact Person</b>
SENTINEL CH. Via Robert Koch, 2 20152 Milan - Italy	Fabio Rota Technical Director +39 02 3455148 Fax: +39 02 34551464

**Date of Preparation of this Summary:** March 28<sup>th</sup>, 2008  
**Device Trade or Proprietary Name:** MULTIGENT Creatinine (Enzymatic)  
**Device Common/Usual Name or Classification Name:** Creatinine Test System  
**Classification Number/Class:** Class II / 862. 1225  
**Product Code:** JFY

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: K073634.

### **Test Description:**

MULTIGENT Creatinine (Enzymatic) Assay is an in vitro diagnostic device for the quantitative determination of creatinine in human serum, plasma, or urine. Creatinine in the sample is hydrolyzed by creatininase to creatine. Creatine is in turn hydrolyzed by creatinase to sarcosine and urea. Sarcosine from this reaction is oxidized by sarcosine oxidase to glycine and formaldehyde, with the concomitant production of hydrogen peroxide. The H<sub>2</sub>O<sub>2</sub> reacts with 4-aminoantipyrine and ESPMT (N-Ethyl-N-sulfopropyl-m-toluidine) in the presence of peroxidase to yield a quinoneimine dye. The resulting change in absorbance at 548 nm is proportional to the creatinine concentration in the sample.

**Substantial Equivalence:**

The MULTIGENT Creatinine (Enzymatic) assay is substantially equivalent to the Roche Creatinine assay (K003261) on the Hitachi 911 Analyzer. Both assays yield similar Performance Characteristics.

**Similarities:**

- Both assays can be used for the quantitative determination of creatinine by means of a calibrated rate assay.
- Both assays utilize calibrators that are traceable to IDMS analysis through values of standard reference materials assigned by this method.
- Both assays are based on the same three-step enzymatic conversion of creatinine to glycine with the concomitant production of hydrogen peroxide.
- Both assays utilize reagents in an R1 and R2 format.
- Both assays yield similar results.
- Both assays use human serum, plasma, and urine

**Differences:**

None

**Intended Use:**

The MULTIGENT Creatinine (Enzymatic) assay is used for the quantitative determination of creatinine in human serum, plasma, or urine.

**Performance Characteristics:**

Comparative performance studies were conducted using the AEROSET System and the ARCHITECT c8000 System. The MULTIGENT Creatinine (Enzymatic) assay method comparison yielded acceptable correlation with the Roche Creatinine Plus assay on the Hitachi 911 Analyzer.

MULTIGENT Creatinine (Enzymatic) - AEROSET System vs. Roche Creatinine Plus - Hitachi 911 Analyzer: This comparison showed a correlation coefficient (r) of 0.999, slope of 1.000, and Y-intercept of -0.015 mg/dL for the serum application, and a correlation coefficient (r) of 0.999, slope of 0.964, and Y-intercept of -1.03 mg/dL for the urine application.

MULTIGENT Creatinine (Enzymatic) - ARCHITECT c8000 System vs. Roche Creatinine Plus - Hitachi 911 Analyzer: This comparison showed a correlation coefficient (r) of 0.999, slope of 1.011, and Y-intercept of -0.100 mg/dL for the serum application and a correlation coefficient (r) of 1.000, slope of 0.986, and Y-intercept of 0.49 mg/dL for the urine application.

MULTIGENT Creatinine (Enzymatic) - ARCHITECT c8000 vs. MULTIGENT Creatinine (Enzymatic) - AEROSET System: This comparison showed a correlation coefficient (r) of 0.999, slope of 1.011, and Y-intercept of -0.079 mg/dL for the serum application and a correlation coefficient of 1.000, slope of 1.022, and Y-intercept of -0.49 mg/dL for the urine application.

Conclusion – Method Comparison: When used on either the AEROSET System or the ARCHITECT c8000 system, the MULTIGENT Creatinine (Enzymatic) assay method yielded acceptable correlation when compared with the Roche Creatinine Plus assay on the Hitachi 911. The MULTIGENT Creatinine (Enzymatic) assay also yielded acceptable cross-platform correlation between the ARCHITECT c8000 System and the AEROSET System.

Precision studies were conducted using the MULTIGENT Creatinine (Enzymatic) assay.

On the AEROSET System, the total %CV values for 20-day inter-assay precision are:

Serum Level 1 (0.647 mg/dL) is 1.95%  
Serum Level 2 (1.826 mg/dL) is 1.30%  
Serum Level 3 (6.606 mg/dL) is 0.72%  
Urine Level 1 (68.769 mg/dL) is 1.31%  
Urine Level 2 (121.937 mg/dL) is 1.23%

On the ARCHITECT c8000 System, the total %CV values for 20-day inter-assay precision are:

Serum Level 1 (0.654 mg/dL) is 3.17%  
Serum Level 2 (1.827 mg/dL) is 1.72%  
Serum Level 3 (6.604 mg/dL) is 0.95%  
Urine Level 1 (69.940 mg/dL) is 1.46%  
Urine Level 2 (124.724 mg/dL) is 1.16%

Analytical Measurement Range (AMR):

The lower linearity limit of the MULTIGENT Creatinine (Enzymatic) assay is 0.08 mg/dL for the serum application, and 2.39 mg/dL for the urine application. The MULTIGENT Creatinine (Enzymatic) assay is linear to 40.73 mg/dL for the serum application and 424.53 mg/dL for the urine application.

Serum AMR Claim: 0.10 to 40.00 mg/dL  
Urine AMR Claim: 2.50 mg/dL to 400.00 mg/dL

**Conclusion for 510(k) Summary:**

These method comparison, precision and AMR data demonstrate that the analytical performance of the MULTIGENT Creatinine (Enzymatic) assay on the ARCHITECT c8000 System and the AEROSET System is substantially equivalent to the performance of the Roche Creatinine Plus assay on the Hitachi 911 Analyzer. Comparability of results between these two methods is established through both the similarity of the procedure and the traceability of calibration through standard reference materials value assigned by IDMS.



Sentinel CH Spa.  
c/o Mr. Fabio Rota  
Technical Director  
Via Robert Koch, 2  
20152 Milano, Italy

**JUN 19 2008**

Re: k073634  
Trade/Device Name: MULTIGENT Creatinine (Enzymatic)  
Regulation Number: 21 CFR 862.1225  
Regulation Name: Creatinine test system  
Regulatory Class: Class II  
Product Code: JFY  
Dated: June 4, 2008  
Received: June 11, 2008

Dear Mr. Rota:

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).

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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

**Indications for Use**

510(k) Number (if known): K073634

Device Name: MULTIGENT Creatinine (Enzymatic)

**Indications For Use:**

The MULTIGENT Creatinine (Enzymatic) assay is a device intended to measure creatinine levels in human serum, plasma, and urine using the ARCHITECT c8000 System and the AEROSET System. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a component of various calculations for determination or estimation of creatinine clearance, glomerular filtration rate (GFR) or estimated GFR (eGFR).

Prescription Use    
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use    
 (21 CFR 801 Subpart C)

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

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

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Carol Benson  
Division Sign-Off

**Office of In Vitro Diagnostic Device  
Evaluation and Safety**

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