JUL 3 2002

Wiener lab.
Especialidades para Laboratorios Clínicos
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Section 6 – Summary

510(k) Summary
"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92"

"The assigned 510(k) number is: K021332 **"**

Introduction	According to the requirements of 21 CFR 862.1215, the following information provides sufficient details to understand the basis of a determination of substantial equivalence.
6-1 Submitter Name, Address, Contact	Wiener Lab Group Riobamba 2944 2000 – Rosario – Argentina Contact person: Viviana Cétola Date Prepared: March 28, 2002.
6-2 Device Name	Proprietary name: WIENER LAB. CK-NAC UV Common name: Creatine Phosphokinase/Creatine Kinase test system. Classification name: NAD Reduction/NADH Oxidation, CPK or Isoenzymes. Device Class II
6-3 Predicate Device	We claim substantial equivalence to the currently marketed DMA CK NAC test system (Cat. Nº 1380-200) and RANDOX CK NAC-activated kit (Cat. Nº CK522).

6-4 Device Description

The reaction system is as follows:

$$\text{Creatine phosphate} + \text{ADP} \xrightarrow{\text{CK}} \text{Creatine} + \text{ATP}$$

$$\text{ATP} + \text{Glucose} \xrightarrow{\text{HK}} \text{ADP} + \text{Glucose-6-P}$$

$$\text{Glucose-6-P} + \text{NADP}^+ \xrightarrow{\text{G-6-PDH}} \text{Gluconate-6-P} + \text{NADPH} + \text{H}^+$$

In the reaction system, NAC works as activator of the Creatine Kinase, recommended by the IFCC.

CK (Creatine Kinase)
HK (Hexokinase)
G-6-PDH (Glucose-6-phosphate dehydrogenase)

6-5 Intended Use

The WIENER LAB. CK-NAC UV test system is a device intended to measure the activity of the enzyme creatine phosphokinase in plasma and serum with manual methodology and automated clinical chemistry analyzers. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

6-6 Equivalencies and differences

The WIENER LAB. CK-NAC UV test system is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed DMA CK NAC test system for the serum application and RANDOX CK NAC-activated system for the plasma application.

The following table illustrates the similarities and differences between the WIENER LAB. CK-NAC UV test system and the currently marketed DMA CK NAC test system.

	DMA Test System	WIENER LAB. Test System
Intended use	Quantitative determination of Creatine Kinase in human serum.	Quantitative determination of Creatine Kinase in human serum and heparinized plasma.
Test principle	The reaction system is as follows: Creatine phosphate + ADP $\xrightarrow{CK}$ Creatine + ATP ATP + Glucose $\xrightarrow{HK}$ ADP + Glucose-6-P Glucose-6-P + $NADP^+$ $\xrightarrow{G\text{-}6\text{-}PDH}$ Gluconate-6-P + NADPH + H^+ In the reaction system, NAC works as activator of the Creatine Kinase, recommended by the IFCC. CK: Creatine Kinase HK: Hexokinase G-6-PDH: Glucose-6-phosphate dehydrogenase	
Essential Components	Creatine phosphate – ADP – Glucose – HK – NAD – G-6PDH – NAC	Creatine phosphate – ADP – Glucose – HK – NADP – G-6PDH – NAC
Reagent Deterioration	Reagent must be a white powder Reagent blank > 0.600 O.D. at 340 nm	Reagent blank > 0.800 O.D. at 340 nm
Working Reagent Stability	Stable 21 days at 2-10ºC	Stable 20 days at 2-10ºC or 3 days at room temperature.
Sample	Human serum	Human serum and heparinized plasma

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	DMA Test System	WIENER LAB. Test System
Working Temperatures	30°C or 37°C	25°C, 30°C or 37°C
Wavelength of reading.	340 nm	334 nm - 340 nm - 366 nm
Linearity	1,500 U/l (30°C) – 2,300 U/l (37°C)	2,000 U/l (37°C)
Instructions for samples exceeding linearity	Dilution in saline and correction of result	
Expected values	7-114 U/l (30°C) 25-160 U/l (37°C)	Male: ≤80 U/l (25°C) ≤130 U/l (30°C) ≤195 U/l (37°C) Female: ≤70 U/l (25°C) ≤110 U/l (30°C) ≤170 U/l (37°C)
Within-run precision	Normal Serum: CV = 2.7% Abnormal Serum: CV = 3.9%	Normal Serum: CV = 2.33% Abnormal Serum: CV = 1.33%
Run-to-run precision	Normal Serum: CV = 2.9% Abnormal Serum: CV = 4.2%	Normal Serum: CV = 2.12% Abnormal Serum: CV = 1.53%

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The following table illustrates the similarities and differences between the WIENER LAB. CK-NAC UV test system and the currently marketed RANDOX CK NAC-activated system.

	RANDOX Test System	**WIENER LAB. Test System**
Intended use	Quantitative determination of Creatine Kinase in human serum, heparinized or EDTA plasma.	Quantitative determination of Creatine Kinase in human serum and heparinized plasma.
Test principle	The reaction system is as follows: Creatine phosphate + ADP $\xrightarrow{CK}$ Creatine + ATP ATP + Glucose $\xrightarrow{HK}$ ADP + Glucose-6-P Glucose-6-P + $NADP^+$ $\xrightarrow{G\text{-}6\text{-}PDH}$ Gluconate-6-P + NADPH + H^+ CK: Creatine Kinase HK: Hexokinase G-6-PDH: Glucose-6-phosphate dehydrogenase	
Essential Components	Creatine phosphate – ADP – Glucose – HK – NADP – G-6PDH – NAC	
Working Reagent Stability	Stable 3 weeks at 2-8°C or 3 days at 15-25°C	Stable 20 days at 2-10°C or 3 days at room temperature.
Sample	Human serum, heparinized or EDTA plasma	Human serum and heparinized plasma

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	RANDOX Test System	WIENER LAB. Test System
Working Reagent Stability	Stable 3 weeks at 2-8°C or 3 days at 15-25°C	Stable 20 days at 2-10°C or 3 days at room temperature.
Sample	Human serum, heparinized or EDTA plasma	Human serum and heparinized plasma
Working Temperatures	25°C, 30°C or 37°C	
Wavelength of reading.	334 nm – 340 nm – 365 nm	334 nm – 340 nm – 366 nm
Linearity	O.D. 0.25 at 340 nm / 334 nm O.D. 0.14 at 365 nm	2,000 U/l (37°C)
Instructions for samples exceeding linearity	Dilution in saline and correction of result	
Expected values	Male: 10-80 U/l (25°C) 15-130 U/l (30°C) 24-195 U/l (37°C) Female: 10-70 U/l (25°C) 15-110 U/l (30°C) 24-170 U/l (37°C)	Male: ≤80 U/l (25°C) ≤130 U/l (30°C) ≤195 U/l (37°C) Female: ≤70 U/l (25°C) ≤110 U/l (30°C) ≤170 U/l (37°C)
Within-run precision	Not stated in insert	Normal Serum: CV = 2.33% Abnormal Serum: CV = 1.33%
Run-to-run precision	Not stated in insert	Normal Serum: CV = 2.12% Abnormal Serum: CV = 1.53%

6-7 Conclusion Based on the above mentioned data, we believe that the extended claims continue to support substantial equivalence to other products in commercial distribution intended for similar use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 3 2002

Dr. Viviana Cetola
QC/QA Manager
Weiner Laboratorios S.A. I.C.
Riobamba 2944
Rosario, Santa Fe
Argentina

Re: k021332
Trade/Device Name: CK-NAC UV
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: CGS
Dated: April 17, 2002
Received: April 26, 2002

Dear Dr. Cetola:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021332

DUPLICATE

510(k) Number (if known): _____

Device Name: Wiener lab.
CK-NAC UV

Indications For Use:

The "Wiener lab. CK-NAC UV" test system is a device intended to measure the activity of the enzyme creatine phosphokinase in plasma and serum with manual methodology and automated clinical chemistry analyzers. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory
510(k) Number K021332

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use___

(Optional Format 1-2-96)