DEC 21 2001

Wiener lab.
Especialidades para Laboratorios Clínicos
WIENER LABORATORIOS S.A.I.C. - Riobamba 2944 - 2000 Rosario - Argentina
Phone +54 (341) 432-9191/6 - Fax +54 (341) 432-5454/5555
Internet: http://www.wiener-lab.com.ar

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: K013652 **"**

Introduction

According to the requirements of 21 CFR 862.1145, 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: August 28, 2001

6-2 Device Name

Proprietary name: WIENER LAB. CA-COLOR AA
Common name: Calcium test system.
Classification name: Cresolphthalein Complexone, Calcium
Device Class II

6-3 Predicate Device

We claim substantial equivalence to the currently marketed POINTE CALCIUM REAGENT SET (Cat. N° C7503-120) for the serum / plasma application and DMA CALCIUM test system (Cat. N° 1250) for the urine application..

6-4 Device Description

Calcium reacts with o-Cresolphtalein complexone (o-CPC) at pH 10.8, yielding a purple colored complex, which is photocolorimetrically measured at 570 nm.
8-hydroxyquinoline is added to remove magnesium interference.

6-5 Intended Use

The WIENER LAB. CA-COLOR AA test system is a quantitative in vitro diagnostic device intended to be used in the quantitative determination of calcium in human sera, heparinized plasmas and urine on both manual and automated systems. Measurements of calcium are used in the diagnosis and treatment of parathyroid diseases, a variety of bone diseases, chronic renal diseases and tetany (intermittent muscular contractions or spasms).

6-6 Equivalencies and Differences

The WIENER LAB. CA-COLOR AA 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 POINTE CALCIUM REAGENT SET for the serum / plasma application and DMA CALCIUM test system for the urine application.

The following table illustrates the similarities and differences between the WIENER LAB. CA-COLOR AA test system and the currently marketed POINTE CALCIUM REAGENT SET.

	POINTE Test System	**WIENER LAB. Test System**
Intended use	Quantitative determination of calcium in human serum and heparinized plasma.	Quantitative determination of calcium in human serum, heparinized plasma and urine.

Continued on next page

	POINTE Test System	WIENER LAB. Test System
Test principle	Calcium reacts with o-Cresolphtalein complexone (o-CPC) at pH 10.8, yielding a purple colored complex, which is photocolorimetrically measured at 570 nm. 8-hydroxyquinoline is added to remove magnesium interference.	
Essential Components	o-CPC 8-hydroxyquinoline	
Reagents	R1: o-CPC / 8-hydroxyquinoline R2: 2-Amino-2-Methyl-1-Propanol / Potassium Cyanide	R1: o-CPC / 8-hydroxyquinoline R2: 2-Amino-2-Methyl-1-Propanol
Reagent Storage	Under refrigeration (2-8°C)	Room temperature
Reagent Deterioration	Turbid reagent	Reagent Blank > 0.400 O.D.
Preparation of Working Reagent	Mixture of R1 and R2 (1:1)	Mixture of R1 and R2 (1:1) or they can be used separately.
Working Reagent Stability	Stable 2 weeks at 2-10°C and 1 week at room temperature.	Stable 4 days at 2-10°C
Precautions	All glassware should be cleaned with diluted hydrochloric acid and rinsed with distilled water.	
Working Temperatures	Room temperature	Room temperature - 37°C
Wavelength of reading.	570 nm	560 – 590 nm

Continued on next page

	POINTE Test System	WIENER LAB. Test System
Linearity	20 mg/dl	
Expected values	Serum 8.5 – 10.5 mg/dl Higher values in children falling to normal with aging.	Serum 8.5-10.5 mg/dl Urine 60-200 mg/24hr
Within-run precision	Normal Serum: CV = 1.5% Abnormal Serum: CV = 1.0%	Normal Level Serum: CV = 1.28% High Level Serum: CV = 1.30% Normal Level Urine CV = 1.06% High Level Urine CV = 0.68%
Run-to-run precision	Normal Serum: CV = 1.4% Abnormal Serum: CV = 2.1%	Normal Level Serum: CV = 1.74% High Level Serum: CV = 1.70% Normal Level Urine CV = 2.50% High Level Urine CV = 1.34%

Continued on next page

The following table illustrates the similarities and differences between the WIENER LAB CREATININA CINETICA AA test system and the currently marketed DMA CALCIUM test system.

	DMA Test System	WIENER LAB. Test System
Intended use	Quantitative determination of calcium in human serum and urine.	Quantitative determination of calcium in human serum, heparinized plasma and urine.
Test principle	Calcium reacts with o-Cresolphtalein complexone (o-CPC) at pH 10.8, yielding a purple colored complex, which is photocolorimetrically measured at 570 nm.	Calcium reacts with o-Cresolphtalein complexone (o-CPC) at pH 10.8, yielding a purple colored complex, which is photocolorimetrically measured at 570 nm. 8-hydroxyquinoline is added to remove magnesium interference.
Essential Components	o-CPC	o-CPC 8-hydroxyquinoline
Reagents	R1: o-CPC / surfactant R2: Diethylamine / Potassium Cyanide	R1: o-CPC / 8-hydroxyquinoline R2: 2-Amino-2-Methyl-1-Propanol
Reagent Storage	Room temperature	

Continued on next page

	DMA Test System	WIENER LAB. Test System
Reagent Deterioration	R1 darkened or with precipitate R2 turbid or colored Reagent Blank > 0.500 O.D.	Reagent Blank > 0.400 O.D.
Preparation of Working Reagent	Mixture of R1 and R2 (1:1) or they can be used separately.	
Working Reagent Stability	Stable 3 days at room temperature.	Stable 4 days at 2-10°C
Precautions	All glassware should be cleaned with diluted hydrochloric acid and rinsed with distilled water.	
Working Temperatures	30°C – 37°C	Room temperature - 37°C
Wavelength of reading.	550 – 585 nm	560 – 590 nm
Linearity	15 mg/dl	20 mg/dl
Expected values	Serum 8.5 – 11.0 mg/dl Urine 100-300 mg/24hr	Serum 8.5-10.5 mg/dl Urine 60-200 mg/24hr
Within-run precision	Normal Serum: CV = 1.98% Abnormal Serum: CV = 1.40%	Normal Level Serum: CV = 1.28% High Level Serum: CV = 1.30% Normal Level Urine CV = 1.06% High Level Urine CV = 0.68%

Continued on next page

	DMA Test System	WIENER LAB. Test System
Run-to-run precision	Normal Serum: CV = 1.93% Abnormal Serum: CV = 2.40%	Normal Level Serum: CV = 1.74% High Level Serum: CV = 1.70% Normal Level Urine CV = 2.50% High Level Urine CV = 1.34%

6-7 Conclusion

Based on the data above mentioned, 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

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 21 2001

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

Re: k013652
Trade/Device Name: Weiner Lab. CA-COLOR AA
Regulation Number: 21 CFR 862.1145
Regulation Name: Calcium test system
Regulatory Class: Class II
Product Code: CIC
Dated: October 15, 2001
Received: November 6, 2001

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

510(k) Number (if known): K013652

K013652

Device Name: Wiener lab.
CA-COLOR AA

Indications For Use:

The "Wiener lab. Ca-Color AA" test system is a quantitative in vitro diagnostic device intended to be used in the quantitative determination of calcium in human sera, heparinized plasmas and urine on both manual and automated systems. Measurements of calcium are used in the diagnosis and treatment of parathyroid diseases, a variety of bone diseases, chronic renal diseases and tetany (intermittent muscular contractions or spasms).

K013652 Marvin C Kuott for Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013652

FDA/CDRH/ODE/DMC
MAY 9 9 26 AM '01
RECEIVED

(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)

CH
11

SK 1