SEP 1 0 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: K021334 **"**

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: July, 2002
6-2 Device Name	Proprietary name: WIENER LAB. CA-COLOR ARSENAZO III AA Common name: Calcium test system. Classification name: Azo Dye, Calcium Device Class II
6-3 Predicate Device	We claim substantial equivalence to the currently marketed WIENER LAB. CA-COLOR AA (Cat. Nº 1152002) kit.

6-4 Device Description

Calcium reacts with Arsenazo III, yielding a blue colored complex, which is photocolorimetrically measured at 650 nm. 8-hydroxyquinoline is added to remove magnesium interference.

6-5 Intended Use

The WIENER LAB. CA-COLOR ARSENAZO III 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 ARSENAZO III 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 WIENER LAB. CA-COLOR AA test system.

The following table illustrates the similarities and differences between the WIENER LAB. CA-COLOR ARSENAZO III AA test system and the currently marketed WIENER LAB. CA-COLOR AA test system.

	CA-COLOR AA	CA-COLOR ARSENAZO III AA
Intended use	Quantitative determination of calcium in human serum, heparinized plasma and urine.	

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	CA-COLOR AA	CA-COLOR ARSENAZO III AA
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	Calcium reacts with Arsenazo III, yielding a blue colored complex, which is photocolorimetrically measured at 650 nm. 8-hydroxyquinoline is added to remove magnesium interference
Essential Components	o-CPC 8-hydroxyquinoline	Arsenazo III 8-hydroxyquinoline
Reagent Storage	Room temperature	2 – 10°C
Reagent Deterioration	Reagent Blank > 0.400 O.D.	Reagent turbidity Reagent Blank > 0.800 O.D.
Preparation of Working Reagent	Mixture of R1 and R2 (1:1) or they can be used separately.	None
Working Reagent Stability	Stable 4 days at 2-10°C	Same as kit stability
Precautions	All glassware should be cleaned with diluted hydrochloric acid and rinsed with distilled water.	
Working Temperatures	Room temperature - 37°C	
Wavelength of reading.	560 – 590 nm	620 – 650 nm

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	CA-COLOR AA	CA-COLOR ARSENAZO III AA
Linearity	20 mg/dl	
Expected values	Serum: 8.5-10.5 mg/dl Urine: 60-200 mg/24hr	
Within-run precision	Normal Level Serum: CV = 1.28% High Level Serum: CV = 1.30% Normal Level Urine CV = 1.06% High Level Urine CV = 0.68%	Normal Level Serum: CV = 1.93% High Level Serum: CV = 0.88% Normal Level Urine CV = 2.57% High Level Urine CV = 1.79%
Run-to-run precision	Normal Level Serum: CV = 1.74% High Level Serum: CV = 1.70% Normal Level Urine CV = 2.50% High Level Urine CV = 1.34%	Normal Level Serum: CV = 1.74% High Level Serum: CV = 1.29% Normal Level Urine CV = 2.44% High Level Urine CV = 2.62%

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

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 0 2002

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

Re: k021334
Trade/Device Name: Ca-Color Arsenazo III AA
Regulation Number: 21 CFR 862.1145
Regulation Name: Calcium test system
Regulatory Class: Class II
Product Code: CJY
Dated: August 1, 2002
Received: August 13, 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

510(k) Number (if known): K021334

Device Name: Wiener lab.
Ca-color Arsenazo III AA

Indications For Use:

The "Wiener lab. Ca-Color Arsenazo III 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).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021334

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