NOV 1 3 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: K013097 **"**

Introduction

According to the requirements of 21 CFR 862.1410, the following information provides sufficient details to understand the basis of a determination of substantial equivalence.

6-1 Submitter Name, Address, Contact

Wiener Laboratorios S.A.I.C.
Riobamba 2944
2000 – Rosario – Argentina
Contact person: Viviana Cétola
Date Prepared: June 20, 2001

6-2 Device Name

Proprietary name: WIENER LAB FER-COLOR AA
Common name: Photometric method for Iron determination.
Classification name: Photometric method, iron (non-heme).
Device Class I
Product Code: JIY

6-3 Predicate Device

We claim substantial equivalence to the currently marketed RANDOX IRON test system.

6-4 Device Description

End point method.

Serum iron is released from its specific carrier protein (transferrin) in a pH 4.5 acetate buffer, and in the presence of a reducing agent (ascorbic acid). Then it reacts with the color reagent, pyridyl bis-phenyl triazine sulfonate (ferrozine) producing a colored complex measured at 570 nm.

6-5 Intended Use

FER-COLOR AA test system is intended to be used in the quantitative determination of iron in human serum and plasma. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease.

6-6 Equivalencies and Differences

WIENER LAB. FER-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 RANDOX IRON test system.

The following table illustrates the similarities and differences between WIENER LAB. FER-COLOR AA test system and the currently marketed RANDOX IRON test system.

	RANDOX Test System	WIENER LAB. Test System
Intended use	Quantitative determination of iron in human serum and plasma	
Test principle	End point method. Serum iron is released from its specific carrier protein (transferrin) in a pH 4.5 acetate buffer. The ferric iron is converted to the ferrous form by the action of a reducing agent (ascorbic acid). Then it reacts with the color reagent, pyridyl bis-phenyl triazine sulfonate (ferrozine) producing a colored complex measured at 540/580 nm.	
Essential Components	Buffer acetate – Ascorbic acid - Ferrozine	
Reagents	R1: Buffer acetate R2: Ascorbic acid – Ferrozine	R1: Ferrozine R2: Buffer acetate R3: Ascorbic acid (reductor)
Preparation of Working Reagent	R1 and R2 ready to use	Preparation of Buffer/ Reductor
Instability or deterioration of reagents	Not specified	Change in Blank and/or Standard Absorbances
Sample	Serum and plasma.	
Working Temperature Range	25 – 37ºC	
Stability of final color	Not specified	5 to 60 minutes

Continued on next page

	RANDOX Test System	WIENER LAB. Test System
Wavelength of reading.	570 nm	540 – 580 nm
Linearity	1000 µg/dl	
Minimum detection limit	Not specified	6.1 µg/dl
Expected values	Male 10.6 – 28.3 µmol/l (59-158 µg/dl) Female 6.6 – 26.0 µmol/l (37-145 µg/dl)	60 -160 µg/dl
Intra-assay precision	Level 1: CV = 2.93% Level 2: CV = 2.29%	Normal Serum Control: CV = 1.32 % Abnormal Serum Control: CV = 0.54%
Inter-assay precision	Not specified	Normal Serum Control: CV =1.75% Abnormal Serum Control: CV = 1.25%

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

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

NOV 1 3 2001

Re: k013097
Trade/Device Name: Fer-Color AA
Regulation Number: 21 CFR 862.1410
Regulation Name: Iron (non-heme) test system
Regulatory Class: Class I, reserved
Product Code: JIY
Dated: July 26, 2001
Received: September 17, 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

K013097

NOV 1 3 2001

510(k) Number (if known): K013097

Device Name: Wiener lab.
Fer-Color AA

Indications For Use:

The "Wiener lab. Fer-Color AA" iron test system is a quantitative in vitro diagnostic device intended to measure iron (non-heme) in serum and plasma. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease.

Jan Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013097

RECEIVED
SEP 17 3:11PM '01
FDA/CDRH/ODE/DCLD

(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)

SK27