SEP 21 2001

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: K012329 **"**

Introduction	According to the requirements of 21 CFR 862.1580, 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 Tel: 54 341 4329191 Fax: 54 341 4851986 Contact person: Viviana Cétola Date Prepared: March 19, 2001

6-2 Device Name

Proprietary name: WIENER LAB ALBUMINA AA

Common name: Albumin test system.

Classification name: Bromcresol Green Dye-Binding, Albumin

Device Class II

6-3 Predicate Device

We claim substantial equivalence to the currently marketed ABBOTT ALBUMIN BCG test system.

6-4 Device Description

Albumin reacts specifically with bromcresol green to produce a colored complex. Increase of absorbance at 625 nm with respect to the reagent Blank is proportional to the albumin concentration in sample.

6-5 Intended Use

The WIENER LAB ALBUMINA AA test system is intended to be used in the quantitative determination of albumin in human sera. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

6-6 Equivalencies and Differences

The WIENER LAB ALBUMINA 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 ABBOTT ALBUMIN BCG test system.

The following table illustrates the similarities and differences between the WIENER LAB ALBUMINA AA test system and the currently marketed ABBOTT ALBUMIN BCG test system.

	ABBOTT Test System	WIENER LAB. Test System
Intended Use	Quantitative determination of albumin in human sera and plasma.	Quantitative determination of albumin in human sera.
Test Principle	Albumin reacts specifically with bromcresol green (BCG) to produce a colored complex. Increase of absorbance at 625 nm with respect to the reagent Blank is proportional to the albumin concentration in sample.	
Essential Components	BCG	
Reagents	Single reagent ready to use	
Storage and Stability of Reagent	Stable until expiration date printed on the labels when stored at room temperature	
Serum Controls	Available - provided separately	
Sample	Human sera and plasmas	Human sera
Wavelength of reading.	600 nm	600 to 650 nm
Linearity	up to 7 g/dl	
Minimum Detection Limit	0.1 g/dl	0.02 g/dl
Analytical sensitivity	0.2 g/dl	0.7 g/dl

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	ABBOTT Test System	WIENER LAB. Test System
Expected values	Male: 4.2-5.5 g/dl Female: 3.7-5.3 g/dl Hospitalized Adult: 3.5-5.0 g/dl	3.5 - 4.8 g/dl
Intra-assay Precision	Normal Serum Control: CV = 1.8 – 1.2 – 1.5% Abnormal Serum Control: CV = 1.7 – 1.4 – 0.8% (in different analyzers)	Normal Serum Control: CV = 2.10 % Abnormal Serum Control: CV = 2.48 %
Inter-assay Precision	Normal Serum Control: CV =2.1 – 1.9 – 2.0 % Abnormal Serum Control: CV = 2.3 – 2.2 – 1.6 % (in different analyzers)	Normal Serum Control: CV = 3.57 % Abnormal Serum Control: CV = 3.99 %

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

SEP 21 2001

Dr. Viviana Cetola
QA/QC Manager
Weiner Laboratories S.A.I.C.
Riobamba 2944
2000 – Rosairo - Argentina

Re: k012329
Trade/Device Name: Albumina AA
Regulation Number: 21 CFR 862.1035
Regulation Name: Albumin Test System
Regulatory Class: Class II
Product Code: CIX
Dated: July 16, 2001
Received: July 23, 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): K012329

Device Name: Wiener lab.
Albumina AA

Indications For Use:

The "Wiener lab. Albumina AA" albumin test system is a quantitative in vitro diagnostic device intended to be used in the quantitative determination of albumin in human sera. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Alexander for Jean Cooper
(Division Sign-
Division of Cl... ...atory Devices
510(k) Number K012329

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)