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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: K012260 **"**

Introduction

According to the requirements of 21 CFR 862.1770, 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
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Contact person: Viviana Cétola
Date Prepared: June 23, 2001

6-2 Device Name

Proprietary name: Wiener lab. UREA UV CINETICA AA
Common name: Urea test system

Classification name: Urease and Glutamic Dehydrogenase, Urea Nitrogen.

Device Class II

6-3 Predicate Device

We claim substantial equivalence to the currently marketed DMA BUN-KINETIC, UREASE PROCEDURE test system (Cat. Nº 1770).

6-4 Device Description

Kinetic method.

The device is based on the following reaction system:

$$\text{Urea} + H_2O \xrightarrow{\text{Urease}} 2\,NH_3 + CO_2$$

$$NH_3 + \text{NADH} + H^+ + \text{2-oxoglutarate} \xrightarrow{\text{GIDH}} \text{l-glutamate} + NAD^+ + H_2O$$

6-5 Intended Use

The UREA UV CINETICA AA test system is intended to be used in the quantitative determination of urea in human serum and plasma. Urea measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.

6-6 Equivalencies and Differences

The WIENER UREA UV CINETICA 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 DMA BUN-KINETIC, UREASE PROCEDURE test system.

The following table illustrates the similarities and differences between the WIENER UREA UV CINETICA AA test system and the currently marketed DMA BUN-KINETIC, UREASE PROCEDURE test system.

	DMA Test System	WIENER LAB. Test System
Intended Use	Quantitative determination of urea in human serum and plasma.	
Test Principle	Kinetic method. The test is based on the following reaction system: $\text{Urea} + H_2O \xrightarrow{\text{Urease}} 2\ NH_3 + CO_2$ $NH_3 + \text{NADH} + H^+ + \text{2-oxoglutarate} \xrightarrow{\text{GIDH}} \text{l-glutamate} + NAD^+ + H_2O$	
Essential Components	2-Oxoglutarate - NADH - Urease - GIDH.	
Working Reagent Stability	14 days	30 days
Instability or deterioration of reagents	Reagent Blank Absorbance < 1.100. Precipitated or hazy standard.	Reagent Blank Absorbance <1.000.
Sample	Human serum, heparinized plasmas and EDTA plasmas	
Working Temperatures	25 - 37ºC	37ºC
Wavelength of reading.	340 nm	
Calibration	Single point	
Linearity	100 mg/dl (BUN) 214 mg/dl (urea)	140 mg/dl (BUN) 300 mg/dl (urea)

Continued on next page

	DMA Test System	WIENER LAB. Test System
Minimum detection limit	0.4 mg/dl (BUN) 0.9 mg/dl (urea)	1.8 mg/dl (BUN) 3.8 mg/dl (urea)
Expected values	8 – 23 mg/dl (BUN) 17 – 49 mg/dl	4.7 – 23 mg/dl (BUN) 10 - 50 mg/dl (urea)
Intra-assay precision	Normal Serum Control: CV = 4.3% Abnormal Serum Control: CV = 4.1%	Normal Serum Control: CV = 2.01% Abnormal Serum Control: CV = 1.19%
Inter-assay precision	Normal Serum Control: CV = 2.9% Abnormal Serum Control: CV = 6.1%	Normal Serum Control: CV = 2.36% Abnormal Serum Control: CV = 1.31%

6-7 Conclusion The date above mentioned show substantial equivalency to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 9 2001

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

Re: k012260
Trade/Device Name: Urea UV Cinetica AA
Regulation Number: 21 CFR 862.1770
Regulation Name: Urea nitrogen test system
Regulatory Class: Class II
Product Code: CDQ
Dated: July 4, 2001
Received: July 18, 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

K012260

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510(k) Number (if known): K012260

Device Name: Wiener lab.
Urea UV cinética AA

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Indications For Use:

The "Wiener lab. Urea UV cinética AA" urea test system is a device intended to measure urea (urea nitrogen) levels in human serum or plasma. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevia Alexander for Joan Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012260

CH II

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)