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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: K030482 **"**

Introduction

According to the requirements of 21 CFR 862.1660, 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: November 15, 2002

6-2 Device Name

Proprietary name: Wiener lab. Standatrol S-E 2 niveles.
Common name: Quality Control Material (assayed and unassayed).
Classification name: Multi-Analyte Controls, all kinds (assayed and unassayed).
Device Class I

6-3 Predicate Device

We claim substantial equivalence to the currently marketed ROCHE Precinorm U and Precipath U (Cat. Nº171735 and 1446096).

6-4 Device Description

Standatrol S-E 2 niveles consists of lyophilized human serum containing the analytes usually determined in clinical chemistry laboratories. The exact concentrations and acceptable ranges of the components are lot-specific and are provided in the product insert.

6-5 Intended Use

Standatrol S-E 2 niveles is a device intended for medical purposes for use in a test system to estimate test precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation. It may also be used for proficiency testing in interlaboratory surveys.
This quality control material is used for monitoring accuracy and precision both for manual techniques and assays on automated clinical chemistry analyzers.

6-6 Equivalencies and Differences

The WIENER LAB. Standatrol S-E 2 niveles is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed ROCHE Precinorm U and Precipath U.

The following table illustrates the similarities and differences between the WIENER LAB. Standatrol S-E 2 niveles quality control material and the currently marketed ROCHE Precinorm U and Precipath U.

	ROCHE Precinorm U and Precipath U.	**WIENER LAB. Standatrol S-E 2 niveles**
Intended Use	For quality control in the quantitative determination of substrates, electrolytes, lipids, enzymes and proteins.	Intended for use as assayed control material for automated and manual clinical chemistry methods.

Continued on next page

	ROCHE Precinorm U and Precipath U.	WIENER LAB. Standatrol S-E 2 niveles
Format	Lyophilized pooled human sera with constituents added as required to obtain desired components levels.	
Stability	Provided Reagents: stable in refrigerator (2-8°C) until expiration date printed on label. Reconstituted control serum: stable for 12 hours at 25°C, 5 days at 4°C or 1 month frozen (-20°C), with exceptions noted in label.	Provided Reagents: stable in refrigerator (2-10°C) until expiration date printed on label. Reconstituted control serum: stable for 5 days at 2 - 10°C or 1 month frozen (-20°C), with exceptions noted in label.
Levels	Two Levels.	
Constituent Analytes and Enzymes	Albumin	Albumin
	Bilirubin, Direct	Bilirubin, Direct
	Bilirubin, Total	Bilirubin, Total
	Calcium	Calcium
	Cholesterol	Cholesterol
	—	HDL-Cholesterol
	Chloride	Chloride
	Creatinine	Creatinine
	Glucose	Glucose
	Iron	Iron
	total Iron-binding capacity	—
	Magnesium	Magnesium
	Inorganic Phosphorus	Inorganic Phosphorus
	Potassium	Potassium
	Protein, total	Protein, total
	Sodium	Sodium

Continued on next page

	ROCHE Precinorm U and Precipath U.	WIENER LAB. Standatrol S-E 2 niveles
Constituent Analytes and Enzymes	Triglycerides	Triglycerides
	Urea	Urea
	Uric acid	Uric acid
	Alkaline Phosphatase	Alkaline Phosphatase
	α-Amylase	α-Amylase
	Alanine Aminotransferase	Alanine Aminotransferase
	Aspartate Aminotransferase	Aspartate Aminotransferase
	Cholinesterase	Cholinesterase
	Creatine Kinase	Creatine Kinase
	γ-Glutamyltransferse	γ-Glutamyltransferse
	Lactate Dehydrogenase	Lactate Dehydrogenase
	Other electrolytes	—
	Other enzymes	—

6-7 Conclusion Above mentioned data show substantial equivalency to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 19 2003

Dr. Viviana Cetola
QC/QA Manager
Weiner Laboratorios S.A. I. C.
Riobamba 2944
2000 Rosario, Santa Fe
Argentina

Re: k030482
Trade/Device Name: Weiner Lab. Standatrol S-E 2 niveles
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: December 30, 2002
Received: February 13, 2003

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

K030482

510(k) Number (if known): K030482

Device Name: Wiener lab.
Standatrol S-E 2 niveles

Indications For Use:

The "Wiener lab. Standatrol S-E 2 niveles" is a device intended for medical purposes for use in a test system to estimate test precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation. It may also be used for proficiency testing in interlaboratory surveys.
This quality control material is used for monitoring accuracy and precision both for manual techniques and assays on automated clinical chemistry analyzers.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030482

Prescription Use X
(Per 21 CFR 801.109)

OR **Over-The-Counter Use** ___

(Optional Format 1-2-96)

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