Wiener lab.
Especialidades para Laboratorios Clínicos
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Section 6 – Summary

FEB 1 2 2003

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: K023992 **"**

Introduction

According to the requirements of 21 CFR 862.3240, 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: September 02, 2002

6-2 Device Name

Proprietary name: Wiener lab. Colinesterasa AA.
Common name: Cholinesterase test system.
Classification name: Colorimetry, Cholinesterase.
Device Class I

6-3 Predicate Device

We claim substantial equivalence to the currently marketed SIGMA DIAGNOSTICS Cholinesterase (BTC) (Cat. 421-10).

6-4 Device Description

Kinetic Method.

The principle is based on the following reaction system:

$$\text{Butyrylthiocholine} + H_2O \xrightarrow{\text{Cholinesterase}} \text{Thiocholine} + \text{Butyrate}$$

$$\text{Thiocholine} + \text{DTNB} \longrightarrow \text{2-Nitro-5-Mercapto-benzoate}$$

The cholinesterase activity is determined by measuring the rate of absorbance change at 405 nm.

DTNB: 5,5´-Dithiobis-2-Nitrobenzoic Acid.
ChE: serum or plasma cholinesterase.

6-5 Intended Use

The WIENER LAB. Colinesterasa AA test system is a quantitative in vitro diagnostic device intended to be used in the quantitative determination of cholinesterase (an enzyme that catalyzes the hydrolysis of acetylcholine to choline) in human specimens, on both manual and automated systems. There are two principal types of cholinesterase in human tissues. True cholinesterase is present at nerve endings and in erythrocytes (red blood cells) but is not present in plasma. Pseudo cholinesterase is present in plasma and liver but is not present in erythrocytes. Measurements obtained by this device are used in the diagnosis and treatment of cholinesterase inhibition disorders (e.g., insecticide poisoning and succinylcholine poisoning).

6-6 Equivalencies and Differences

The WIENER LAB. Colinesterasa 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 SIGMA DIAGNOSTICS Cholinesterase (BTC) test system.
The following table illustrates the similarities and differences between the WIENER LAB. Colinesterasa AA test system and the currently marketed SIGMA DIAGNOSTICS Cholinesterase (BTC) test system.

	Cholinesterase (BTC)	Colinesterasa AA
Intended Use	For the quantitative, kinetic determination of cholinesterase activity in serum at 405 nm.	Kinetic method at 405 nm for the determination of cholinesterase in serum or plasma.
Test Principle	Kinetic Method. The principle is based on the following reaction system: Butyrylthiocholine + H_2O —Cholinesterase→ Thiocholine + Butyrate Thiocholine + DTNB ⟶ 2-Nitro-5-Mercapto-benzoate The cholinesterase activity is determined by measuring the rate of absorbance change at 405 nm. DTNB: 5,5´-Dithiobis-2-Nitrobenzoic Acid. ChE: serum or plasma cholinesterase.	
Reagents	Cholinesterase (BTC) Reagent: Butyrylthiocho-line iodide – DTNB – Buffer.	Reagent 1: DTNB – Phosphate buffer. Reagent 2: Butyrylthiocholine. Diluent 1 and 2: aqueous solution.
Preparation of Working Reagent	Reconstitute Cholinesterase (BTC) Reagent with indicated volume of deionized water	Reconstitute each Reagent 1 and 2 vial with stated volume of Diluent 1 and 2 respectively.
Wavelength of Reading	405 nm	
Linearity	13000 U/l for a Sample/Reagent Ratio 1:300	17000 U/l

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	Cholinesterase (BTC)	Colinesterasa AA
Expected values	3200 – 7700 U/l at 30°C	Children, men and women over 40 years old: 5500 - 13400 U/l (37°C) Women between 16 - 39 years old, non pregnant and not ingesting oral contraceptives: 4400 - 11700 U/l (37°C) Women between 18 - 41 years old, pregnant or ingesting oral contraceptives: 3800 - 9500 U/l (37°C)
Within-run precision	Normal Level Serum: CV = 2.0% High Level Serum: CV = 1.8%	Normal Level Serum: CV = 1.41% High Level Serum: CV = 0.97%
Total precision	Normal Level Serum: CV = 4.2% High Level Serum: CV = 2.6%	Normal Level Serum: CV = 2.00% High Level Serum: CV = 1.97%

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 12 2003

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

Re: k023992
Trade/Device Name: Wiener Lab. Colinesterasa AA
Regulation Number: 21 CFR 862.3240
Regulation Name: Cholinesterase test system
Regulatory Class: Class I
Product Code: DIH
Dated: January 20, 2003
Received: January 22, 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

510(k) Number (if known): K023992

Device Name: Wiener lab.
Colinesterasa AA

Indications For Use:

The "Wiener lab. Colinesterasa AA" test system is a quantitative in vitro diagnostic device intended to be used in the quantitative determination of cholinesterase (an enzyme that catalyzes the hydrolysis of acetylcholine to choline) in human serum or plasma, on both manual and automated systems. There are two principal types of cholinesterase in human tissues. True cholinesterase is present at nerve endings and in erythrocytes (red blood cells) but is not present in plasma. Pseudo cholinesterase is present in plasma and liver but is not present in erythrocytes. Measurements obtained by this device are used in the diagnosis and treatment of cholinesterase inhibition disorders (e.g., insecticide poisoning and succinylcholine poisoning).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023992

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

(Optional Format 1-2-96)