K061093

510(k) Summary

JUL - 3 2006

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
317-521-3723

Contact Person: Theresa M. Ambrose

Date Prepared: April 18, 2006

Device Name

Proprietary name: Cholinesterase Gen.2 test system

Common name: Cholinesterase

Classification name: Cholinesterase test system.

Predicate devices

The Cholinesterase Gen.2 test system is substantially equivalent to the currently marketed Cholinesterase Test System cleared under K951595.

Device Description

The Cholinesterase Gen.2 Test System is an in vitro test for the quantitative determination of the catalytic activity of cholinesterase in serum and plasma. The test is based on the butyrylthiocholine method. Cholinesterase catalyzes the hydrolysis of butyrylthiocholine to thiocoline and butyrate. Thiocholine reduces the yellow substrate hexacyanoferrate III to the almost colorless hexacyanoferrate II. The decrease in color is measured spectrophotometrically. The calibrator is the Calibrator for automated systems (C.f.a.s; and the recommended control materials are Precinorm U or Precinorm U Plus; and Precipath U or Precipath U plus.

510(k) Summary, **Continued**

Intended use

The Cholinesterase Gen.2 Test System is an in vitro test for the quantitative determination of the catalytic activity of cholinesterase (EC 3.1.1.8; acycholine acylhydrolase) in serum and plasma.

Comparison to predicate device

The below table compares the Cholinesterase Gen.2 Test System with the predicate device, Cholinesterase (K951595)

Substantial equivalence: comparison table

Characteristic	**Cholinesterase Gen.2 Test System**	**Predicate device Cholinesterase Test System (K951595)**
Intended Use	for the quantitative determination of the catalytic activity of cholinesterase (EC 3.1.1.8; acycholine acylhydrolase) in serum and plasma.	for use on COBAS INTEGRA for the quantitative determination of the catalytic activity of cholineseterase cholinesterase (EC 3.1.1.8; acycholine acylhydrolase) in serum and plasma.
Assay principle	Detection of catalytic activity via spectrophotometric detection of product. Butyrylthiocholine is hydrolyzed by cholinesterase; product reduces a yellow substrate resulting in a colorless product.	Detection of catalytic activity via spectrophotometric determination of product. S-butyrlthicholine iodide is hydrolyzed by cholinesterase; product reacts with DTNB resulting in yellow product.
Instrument	same	COBAS Integra family of analyzers (Integra 400/ 700/ 800)
Reagent Stability	• Unopened kit: up to the stated expiration date at 2-8 °C • On board the analyzer: 4 weeks	• Unopened kit: up to the stated expiration date at 2-8 °C • On board the analyzer : 8 weeks
Reagent format	liquid	granulate
Reagent composition	R1: Pyrophosphate, Potassium hexacyanoferrate R2: Butyrlthiocholine, GOOD's buffer, stabilizers	R1: Phosphate, DTNB (5,5' -dithiobis-2-nitrobenzoate R2: s-butyrlthiocholine iodide
Sample type	Same	Human serum and plasma (EDTA, heparin)

Traceability/ standardization	Standardized against a reference method using a manual application of the butyrlthiocholine/ hexacyanoferrate (III) method on a photometer and the published molar absorptivity of hexacyanoferrate (III)	Manually against an internally prepared reagent.

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Comparison to predicate (continued)

Characteristic	Cholinesterase Gen.2 Test System	Predicate device Cholinesterase Test System (K951595)
Measuring range	200-14000 U/L Extended range after postdilution: 200 -28000 U/L	0—25000 U/L
Lower Detection Limit	200 U/L	4.5 U/L
Within-run precision (%CV)	• 0.5% at 6374 U/L • 0.6% at 6263 U/L • 0.6% at 6015 U/L	• 1.0 % at 1728 U/L • 0.99 % at 9545 U/L
Between-run precision (%CV)	• 1.4% at 6374 U/L • 1.1% at 6263 U/L • 0.9% at 6015 U/L	• 2.2 % at 1728 U/L • 1.8 % at 9545 U/L (total CV)
Limitations: interferences	No significant interference from bilirubin. No significant interference up to • H index of 350 (hemoglobin 350 mg/dL) • L index of 1000 (lipemia) Citrate and fluoride inhibit the reaction and must not be used. No significant interference from tested drugs. In rare cases, monoclonal gammopathy, in particular typw IgM (Waldenstrom's macroglobulinemia) may cause unreliable results. For diagnostic purposes, results should always be assessed in conjunction with the patient's medical history and other findings.	No significant interference from hemolysis, icterus, lipemia. Citrate and fluoride inhibit the reaction and must not be used. Propanolol causes artificially low cholinesterase values at the tested level. Pathologically high levels of albumin (7 g/dL) increase the apparent cholinesterase activity significantly

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Comparison to predicate (continued)

Characteristic	Cholinesterase Gen.2 Test System	Predicate device Cholinesterase Test System (K951595)
Expected values	Children, men, women aged 40 or more: 5320 – 12920 U/L Women aged 16-39, not pregnant, not using hormonal contraceptives: 4260-11250 Women aged 18-41, pregnant or taking contraceptives: 3650-9120 U/L	Females 3000 – 103000 U/L Males 3500 – 114000 U/L
Method comparison	y = Integra Cholinesterase Gen.2 x = Integra cholinesterase (granulate) Passing-Bablok results: y=0.970x + 128. T = 0.967; r = 0.999	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Theresa M. Ambrose
Regulatory Affairs Principal
Roche Diagnostics
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Indianapolis, IN 46250

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Re: k061093
Trade/Device Name: Cholinesterase Gen.2 Test System
Regulation Number: 21 CFR§ 862.3240
Regulation Name: Cholinesterase test system
Regulatory Class: Class I
Product Code: DIH
Dated: April 18, 2006
Received: April 19, 2006

Dear Ms. Ambrose:

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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061093

Device Name: Cholinesterase Gen.2

Indications For Use:

The Cholinesterase Gen.2 Test System is an in vitro test for the quantitative determination of the catalytic activity of cholinesterase (EC 3.1.1.8; acylcholine acylhydrolase) in serum and plasma.
Measurements obtained by this device are used in the diagnosis and treatment of cholinesterase inhibition disorders.

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office [illegible] c Device Evalu[illegible]

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