K040245

MAR 2 4 2004

510(k) Summary

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: February 2, 2004

Device Name

Proprietary name: Calibrator for Automated Systems Prealbumin-ASLO-Ceruloplasmin (C.f.a.s. PAC)

Common name: C.f.a.s. PAC

Classification name: Calibrator, Multi-analyte mixture

Predicate device

The C.f.a.s. PAC is substantially equivalent to the currently marketed C.f.a.s. Lipids (K011658).

Device Description

The C.f.a.s. PAC is a lyophilized product consisting of human serum with biological materials added as required to obtain desired component levels. Values for constituent analytes are provided in product labeling.

Intended use

The C.f.a.s. PAC is intended for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.

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Comparison to predicate device

The C.f.a.s. PAC is substantially equivalent to the currently marketed C.f.a.s. Lipids (K011658). The below tables compare C.f.a.s. PAC with the predicate device, C.f.a.s. Lipids (K011658).

Similarities

Characteristic	C.f.a.s. PAC	Predicate device C.f.a.s. Lipids (K011658)
Intended Use	C.f.a.s. PAC is intended for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.	C.f.a.s. Lipids is intended for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.
Format	Lyophilized	same
Matrix	Human serum	same
Handling	Reconstitute with exactly 1.0 mL distilled/ deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes.	same
Levels	Single level	same

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Differences

Characteristic	C.f.a.s. PAC	Predicate device C.f.a.s. Lipids (K011658)
Analytes	• Prealbumin • Antistreptolysin O (ASLO) • Ceruloplasmin	• Apolipoprotein A1 • Apolipoprotein B • HDL-cholesterol • LDL-cholesterol
Stability	Unopened: stable up to the stated expiration date Reconstituted: • 15 to 25 °C: 8 hours • 2 to 8 °C: 2 days • -15 to -25 °C: 2 weeks (when frozen once)	Unopened: stable up to the stated expiration date Reconstituted: • 15 to 25 °C: 8 hours • 2 to 8 °C 5 days • -15 to -25 °C 4 weeks (when frozen once)

Performance Characteristics

- The C.f.a.s. PAC was evaluated for value assignment and stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 4 2004

Theresa M. Ambrose, Ph.D, DABCC, FACB, RAC
Regulatory Principal
Centralized Diagnostics Regulatory Submissions
Roche Diagnostics Corp.
9115 Hague Rd.
Indianapolis, IN 46250

Re: k040245
Trade/Device Name: C.f.a.s. PAC
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: February 2, 2004
Received: February 03, 2004

Dear Dr. 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 (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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
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 Statement

510(k) Number (if known): N/A K040245

Device Name: C.f.a.s. PAC

Indications For Use:
The C.f.a.s. PAC is intended for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.

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

(Optional Format 1-2-96)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040245