K011658

JUL 3 1 2001

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 Corporation
9115 Hague Road
Indianapolis, IN 46250
(317) 576-7643

Contact Person: Helen T. Torney

Date Prepared: May 24, 2001

Device Name

Proprietary name: Calibrator for Automated Systems (C.f.a.s.) Lipids

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

Classification name: Calibrator, Multi-analyte mixture

Device Description

The Calibrator for Automated Systems (C.f.a.s.) consists of liquid human serum with biological materials added as required to obtain desired component levels. Values for constituent analytes are provided in product labeling.

510(k) Summary, Continued

Intended use

For use in the calibration of Roche lipid methods on automated clinical chemistry analyzers.

Substantial Equivalence

The Calibrator for Automated Systems (C.f.a.s.) Lipids is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Roche Diagnostic Calibrator for Automated Systems (C.f.a.s.) HDL/LDL-C plus (K974825). The intended use of both devices is the establishment of calibration curves for their respective test systems.

Substantial equivalence - similarities

The following table compares the Calibrator for Automated Systems (C.f.a.s.) Lipids with the predicate device.

Feature	C.f.a.s. Lipids	C.f.a.s. HDL/LDL-C plus (Predicate Device)
Intended Use	For use in the calibration of Roche lipid methods on automated clinical chemistry analyzers.	For use in the calibration of homogeneous Roche methods for the quantitative determination of HDL-cholesterol and LDL-cholesterol on automated clinical chemistry analyzers.
Format	Pooled human sera with constituents added as required to obtain component levels.	Pooled human sera with constituents added as required to obtain desired component levels.
Stability	• Stability of lyophilized calibrator at 2-8°C. until expiration date. • Stability of reconstituted calibrator: 8 hours at 15-25°C. 5 days at 2-8°C. 1 month at -20°C.	• Stability of lyophilized calibrator at 2-8°C until expiration date. • Stability of reconstituted calibrator: 1 day at 15-25°C. 5 days at 2-8°C. 1 month at -20°C.
Levels	Single Level	Single Level
Matrix	Lyophilized	Lypophilized

Substantial equivalence – differences

Comparison of proposed Calibrator for Automated Systems (C.f.a.s.) Lipids and predicate device.

Feature	C.f.a.s. Lipids	C.f.a.s. HDL/LDL-C plus (Predicate Device)
Constituent Analytes	Apolipoprotein A 1	HDL-cholesterol
	Apolipoprotein B	LDL-cholesterol
	Cholesterol	
	HDL-cholesterol	
	LDL-cholesterol	
	Phospholipids	
	Triglycerides	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 3 1 2001

Ms. Helen T. Torney
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
PO Box 50457
Indianapolis, IN 46250-0457

Re: 510(k) Number: K011658
Trade/Device Name: Calibrator for Automated Systems (C.f.a.s.) Lipids
Regulation Number: 862.1150
Regulatory Class: II
Product Code: JIX
Dated: May 24, 2001
Received: May 29, 2001

Dear Ms. Torney:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 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

JUL 3 1 2001

Indications for Use Statement

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

Device Name: Calibrator for Automated Systems (C.f.a.s.) Lipids

Indications For Use:

For use in the calibration of Roche lipid methods on automated clinical chemistry analyzers.

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011658