3/22/99

K990460

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 Rd Indianapolis, IN 46250 (317) 576-3723 Contact person: Priscilla A. Hamill Date prepared: February 10, 1999
Device name	**Proprietary name**: Calibrator for Automated Systems (C.f.a.s.) **Common name**: C.f.a.s. **Classification name**: Calibrator, Multi-analyte mixture
Predicate device	We claim substantial equivalence to Roche Serum Calibrator.
Device description	The Calibrator for Automated Systems (C.f.a.s.) consists of lyophilized 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 Calibrator for Automated Systems (C.f.a.s.) is intended for use as a calibrator of clinical chemistry assays. The material is well suited for automated analytical procedures.

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Comparison to the predicate device

The Calibrator for Automated Systems (C.f.a.s.) calibrator is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Roche Serum Calibrator.

The intended use of this calibrator and the predicate devices is the same in that they are intended to be used for the calibration of test systems for the measurement of their labeled analytes.

Substantial equivalence -- similarities

The chart below illustrates the similarities between Calibrator for Automated Systems (C.f.a.s.)and the predicate device.

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

Characteristic	C.f.a.s. (Modified Device)	Roche Calibrator Serum (Predicate Device)
Intended Use	For use as a calibrator of clinical chemistry assays for automated analytical procedures.	For use on COBAS systems and manual determinations with Roche reagents to establish points of reference
Format	Lyophilized pooled human sera with constituents added as required to obtaine desired component levels	Lyophilized pooled human serum with constituents added as required to obtain desired component levels
Stability	• Stable at 2-8° C until expiration date • Stable 2 days when reconstituted, stoppered, protected from light and stored at 2-8° C, with exceptions noted in labeling.	• Stable at 2-8° C until expiration date • Stable 2 days when reconstituted, stoppered, protected from light and stored at 2-8° C, with exceptions noted in labeling.
Levels	Single Level	Single Level

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Substantial equivalence -- differences

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

Constituent Analytes

C.f.a.s. (Modificed Device)	Roche Calibrator Serum (Predicate Device)
Acid Phosphatase	Acid Phosphatase
Alkaline Phosphatase	Alkaline Phosphatase
Alanine Aminotransferase	Alanine Aminotransferase
α-Amylase	α-Amylase
Aspartate Aminotransferase	Aspartate Aminotransferase
Cholinesterase	Cholinesterase
Creatine Kinase	Creatine Kinase
γ-Glutamyltransferase	γ-Glutamyltransferase
Lactate Dehydrogenase	Lactate Dehydrogenase
Lipase	Lipase
Albumin	Albumin
Bilirubin (Direct)	Bilirubin (Direct)
Bilirubin (Total)	Bilirubin (Total)
Calcium	Calcium
Cholesterol	Cholesterol
Creatinine	Creatinine
Glucose	Glucose
Iron	Iron
Magnesium	Magnesium
Phosphorus (Inorganic)	Phosphorus (Inorganic)
Total Protein	Total Protein
Triglycerides	Triglycerides
Uric Acid	Uric Acid
Urea (BUN)	Urea (BUN)
Sodium	
Potassium	
Chloride	
Bicarbonate	
UIBC	
LD1	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 22 1999

Priscilla A. Hamill
Regulatory Affairs Consultant
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: K990460
Trade Name: Calibrator for Automated Systems (C.f.a.s.)
Regulatory Class: II
Product Code: JIX
Dated: February 10, 1999
Received: February 12, 1999

Dear Ms. Hamill:

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 (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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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"(21 CFR 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

510(k) Number (if known): K990460

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

Indications for Use:
For use as a calibrator of clinical chemistry assays. Biological materials are added as required to obtain desired component levels. This calibrator material is well suited for automated analytical procedures. Levels of constituent analytes are provided in product labeling.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990460

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ___
(Per 21 CFR 801.109)

(Optional format 1-2-96)