DEC - 9 1999

K993829

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.
1) Submitter name, address, contact	Roche Diagnostics Corporation 9115 Hague Rd. Indianapolis, IN 46250 (317) 845-2000 Contact Person: Mike Flis Date Prepared: November 09, 1999
2) Device name	Proprietary name: Accu-Chek Simplicity™ System Common name: whole blood glucose test system Classification name: Glucose dehydrogenase, glucose
3) Predicate device	We claim substantial equivalence to the current legally marketed version of the same device.
4) Device Description	Instrument Operating Principle -- photometric Reagent Test Principle -- glucose deoxy reductase
5) Intended use	The test strips are to be used with the Accu-Chek Simplicity meter. The Accu-Chek Simplicity system is designed for testing glucose in whole blood by persons with diabetes or by health care professionals in the home or in health care facilities.
6) Comparison to predicate device	The Roche Diagnostics Accu-Chek Simplicity System is substantially equivalent to the current legally marketed version of the same device.

Comparison to Predicate Device

Similarities

Feature/Claim	Detail
Intended use	The test strips are to be used with the Accu-Chek Simplicity meter. The Accu-Chek Simplicity system is designed for testing glucose in whole blood by persons with diabetes or by health care professionals in the home or in health care facilities.
Test principle	Glucose dehydrogenase chemical reaction. The instrument measures the chemical reaction by detecting photometric changes.
Monitor coding procedure	Code chip is provided with each carton of test strips.
Minimum sample volume	3 µL
Test strip storage conditions	Store the strips at room temperature between +36° F and +86° F. Do not freeze.
Test strip operating conditions	Use at temperatures between 50° and 104° F and less than 85% humidity.
Quality control procedure	Tests should be run with liquid quality control materials whenever a new vial of test strips is opened or an unusual blood test result is obtained.
Labeling instructions regarding expected results	The normal fasting adult blood glucose range for a non-diabetic is 70-105 mg/dL. One to two hours after meals, normal blood glucose levels should be less than 140 mg/dL. Doctors will determine the range that is appropriate for the patients.
Labeling instructions regarding response to unusual results	Run a quality control test, if the result is outside the acceptable QC recovery range contact Roche Diagnostics's Accu-Chek Customer Care center; if result is within the acceptable range, review proper testing procedure and repeat blood glucose test with a new test strip.
Hematocrit range	30 to 57%
Reportable range	10-600 mg/dL
Warnings and precautions	For *in vitro* diagnostic use only.
Reagent stability	18 months

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Comparison to Predicate Device, Continued

Similarities, Contd.

Reagent composition	Copied from test strip carton label (qty/cm^2): Glucose-dye-oxidoreductase.....0.4 U Bis-(2-hydroxyethyl)-(4-hydroxminocyclohexa-2,5-dienylidene)-ammonium chloride.....19.3 µg 2,18-Phosphomolybdic acid.....328.0 µg Stabilizer.....0.31 mg Nonreactive substances.....4.4 mg Minimum at time of manufacture.

Differences

Feature	Accu-Chek Simplicity Test Strip (modified)	Accu-Chek Simplicity Test Strip (predicate)
Values equivalent to...	plasma lab method	whole blood method
Maximum altitude	Tested acceptably at elevations up to 10,150 feet above sea level[1]	Tested acceptably at elevations up to 9500 feet above sea level.
Acceptable sample type	Fresh capillary whole blood only[2]	Fresh capillary and heparinized venous whole blood samples

1. The effect of altitude was examined at a different clinical investigation site than K971876. The site selected for the most recent examination was higher than the prior site. The results of the 1999 study confirm the device performs acceptably at 10,150 feet.
2. The proposed modification does not adversely effect the product's performance with heparinized whole blood samples. The removal of the venous sample claim from the product's labeling is triggered by our desire to position this device as a test best suited for consumer testing. The draft labeling only includes references to capillary fingerstick testing procedures and summaries of results obtained in capillary blood clinical studies.

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Comparison to Predicate Device, Continued

Performance Characteristics

Method Comparison

Feature	Accu-Chek Simplicity Test Strip Package Insert (modified)	Accu-Chek Simplicity Test Strip Package Insert (predicate)
Laboratory method	Hitachi glucose plasma	Hitachi glucose hexokinase whole blood
Capillary blood study	N = 297 y = 1.02x – 5.2 r = 0.977 r ange = 57 to 515 mg/dL	N = 202 y = 1.02x + 2.6 r = 0.989 range = 51 to 490 mg/dL
Physician's Office Venous blood study	Not applicable	N = 104 y = 1.029x + 2.7 r = 0.995 range = 35 to 483 mg/dL
Consumer study	N = 230 y = 1.05x – 7.0 r = 0.982 range = 57 to 515 mg/dL	N = 134 y = 1.082x – 2.9 r = 0.976 range = 58 to 357 mg/dL

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Comparison to Predicate Device, Continued

Performance Characteristics, Contd.

Precision

Parameter	Accu-Chek Simplicity Test Strip Package Insert (modified)	Accu-Chek Simplicity Test Strip Package Insert (predicate)
	N = 20/Level	N = 20/Level
Control Level 1		
•Mean (mg/dL)	52	84.0
•Standard Deviation (SD) (mg/dL)	1.6	2.0
Control Level 2		
•Mean (mg/dL)	167	196.4
•Standard Deviation (SD) (mg/dL)	4.7	
•CV	2.8	2.5
Venous Blood Level 1		
•Mean (mg/dL)	53	28.7
•Standard Deviation (SD) (mg/dL)	1.7	1.2
Venous Blood Level 2		
•Mean (mg/dL)	153	129.4
•Standard Deviation (SD) (mg/dL)	6.3	
•CV	4.1	3.0
Venous Blood Level 3		
•Mean (mg/dL)	499	335.0
•Standard Deviation (SD) (mg/dL)	16.3	
•CV	3.3	3.4

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 9 1999

Mr. Mike Flis
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K993829
Trade Name: Accu-Chek Simplicity™ System
Regulatory Class: II
Product Code: LFR
Dated: November 10, 1999
Received: November 12, 1999

Dear Mr. Flis:

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

Indications for Use Statement

510(k) Number (if known): K993829
Device Name: Accu-Chek Simplicity™ System

Indications for Use:

The test strips are to be used with the Accu-Chek Simplicity meter. The Accu-Chek Simplicity system is designed for testing glucose in whole blood by persons with diabetes or by health care professionals in the home or in health care facilities.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993829

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