K051592

SEP - 2 2005

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) 521-7688
Contact Person: Dimitris Demirtzoglou
Date Prepared: June 14, 2005

2) Device name

Proprietary name: Accu-Chek Go System
Classification name: Glucose dehydrogenase, glucose test system (21 C.F.R. § 862.1345)(75LFR)

3) Predicate device

We claim substantial equivalence to the current legally marketed Accu-Chek Go System (K#040796).

4) Device Description

Instrument Operating Principle -- photometry
Reagent Test Principle -- glucose dehydrogenase

5) Intended use

The Accu-Chek Go system is designed to quantitatively measure the concentration of glucose in whole blood by persons with diabetes or by health care professionals for monitoring glucose in the home or in health care facilities. The device is indicated for professional use and over-the-counter sale.

Professionals may use the test strips to test capillary, venous and arterial blood samples; lay use is limited to capillary whole blood testing. Capillary blood samples can be acquired from fingertips, forearm, upper arm, thigh, calf and palm.

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6) Similarities The Roche Diagnostics Accu-Chek Go (modified) System is substantially equivalent to the current legally marketed Accu-Chek Go (predicate) System. The proposed modification is relatively modest in scope. The following is a list of some of the claims and features unaffected by the proposed modification.

Feature/Claim	Detail
Test principle	A glucose dye oxidoreductase mediator reaction. **Step 1:** Glucose is oxidized by the PQQ-dependent enzyme glucoe-dye-oxidoreductase (EC.1.1.99.17) to gluconolactone and the reduction equivalents are transferred to the enzyme-bound PQQ to give $PQQH_2$. **Step 2:** The enzyme transfers the reduction equivalents from $PQQH_2$ to the oxidized form of the mediator. Bis-(2-hydroxyethyl)-(4-hydroximinocyclohexa-2,5-dienylidene)-ammonium-chloride is used as a mediator. **Step 3:** The reduced form of the mediator reduces the indicator 2,18-phosphomolybdic acid to produce the color heteropolyblue.
Test strip storage conditions	Store at room temperature between +36° F (+2° C) and +86° F (+30° C).
Test strip operating conditions	Between +5° F (+10° C) and +104° F (+40° C).
Quality control testing frequency	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.
Quality control acceptable range	The mean is strip lot specific and will be determined individually. The range of the controls is within ± 15 mg/dL or ± 15% compared to the determined mean.
Labeling instructions regarding expected results	The normal fasting adult blood glucose range for a non-diabetic is 74-106 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 Diagnostic'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.
Reportable range	10-600 mg/dL
Hematocrit range	25 – 65%
Warnings and precautions	For *in vitro* diagnostic use only.

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510(k) Summary, Continued

6) Similarities **(continued)**

Feature/Claim	Detail
Reagent stability	18 months
Data transmission to external devices	Infrared interface
Reagent composition	• Bis-(2-hydroxyethyl)-(4-hydroximinocyclohexa-2,5-dienylidene)-ammonium-chloride • Glucose dye oxidoreductase* • 2,18-phosphomolybdic acid • Stabilizer • Nonreactive ingredients *(*from A. Calcoaceticus, recombinant from E. Coli*)
Alternate Site Test (AST) Claim	Both meter systems claim six testing sites, including: fingertip, upper arm, forearm, thigh, calf, and palm. • Both meter systems include the same precautionary messaging relative to AST in the associated labeling. • Both meter systems utilize the same optical detection system. • Both meter systems utilize the same under dose detection technology and scheme. • Both test strips have the same architecture and functional structure.
Meter physical dimensions	113 x 46 x 20 mm
Batteries required	1 lithium battery type CR2430 or DL2430
Data Memory Capacity	300 blood glucose results with date and time
Monitor coding procedure	Code chip provided with each carton of test strips.
Test time	Approximately 5 seconds
Method of preparing a test strip for a glucose test	User extracts a single test strip from a test strip vial and inserts the strip into the appropriate port in the meter until positioned correctly for a test.

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Differences

Feature	Accu-Chek Go (modified)	Accu-Chek Go (predicate)
Intended use	The Accu-Chek Go system is designed to quantitatively measure the concentration of glucose in whole blood by persons with diabetes or by health care professionals for monitoring glucose in the home or in health care facilities. The device is indicated for professional use and over-the-counter sale. Professionals may use the test strips to test capillary, venous and arterial blood samples; lay use is limited to capillary whole blood testing	The Accu-Chek Go system is designed to quantitatively measure the concentration of glucose in capillary whole blood by persons with diabetes or by health care professionals in the home or in health care facilities. The device is indicated for professional use and over-the-counter sale. Professionals may use the test strips to test capillary and venous blood samples; lay use is limited to capillary whole blood testing.
Acceptable sample types	Capillary whole blood samples from a finger stick or AST site. Venous and arterial blood may also be used only if drawn by health care professionals.	Capillary whole blood samples from a finger stick or AST site. Venous blood may also be used only if drawn by health care professionals.

7) Data demonstrating substantial equivalence

Performance testing on the modified Accu-Chek Go System demonstrated that the device meets the performance requirements for its intended use. A multi-center performance study was conducted to evaluate the accuracy and precision of the modified device. The study's objective was to evaluate the extent, to which results obtained from the system correlate to whole blood glucose reference that has been converted to a plasma-like result, using arterial whole blood. The clinical data demonstrates that the performance of the Accu-Chek Go correlates well with the laboratory plasma glucose reference test method, Glucose Hexokinase. All predetermined acceptance criteria were satisfied. The data also demonstrates that the Accu-Chek Go is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 2 2005

Mr. Dimitris Demirtzoglou
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50416
Indianapolis, IN 46250

Re: k051592
Trade/Device Name: Accu-Chek Go test system
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, LFR
Dated: June 14, 2005
Received: June 15, 2005

Dear Mr. Demirtzoglou:

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,

Carol C. Benson

Carol C. Benson, M.A.
Acting 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): K051592

Device Name: Accu-Chek Go Test System

Indications For Use:

The Accu-Chek Go system is designed to quantitatively measure the concentration of glucose in whole blood by persons with diabetes or by health care professionals for monitoring glucose in the home or in health care facilities. The device is indicated for professional use and over-the-counter sale.

Professionals may use the test strips to test capillary, venous and arterial blood samples; lay use is limited to capillary whole blood testing.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) (AND/OR) Over-The-Counter Use __X___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K051592