K031755

JUL 0 3 2003

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: Scott Thiel
Date Prepared: June 3, 2003, 2003

2) Device name

Proprietary name: Accu-Chek Compact 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 version of the same device.

4) Device Description

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

5) Intended use

The Accu-Chek Compact Test Drums are used with the Accu-Chek Compact Meter. The Accu-Chek Compact system is designed to quantitatively measure the concentration of glucose in capillary and venous whole blood. The device is indicated for professional use and over-the-counter sale. The Accu-Chek Compact system is indicated for lay person use with capillary whole blood samples drawn from the fingertips, forearm, upper arm, thigh, calf, and palm.

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6) Similarities The Roche Diagnostics Accu-Chek Compact Test Strip is substantially equivalent to the current legally marketed version of the same device. 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
Intended use	The Accu-Chek Compact Test Drums are used with the Accu-Chek Compact Meter. The Accu-Chek Compact system is designed to quantitatively measure the concentration of glucose in capillary and venous whole blood. The device is indicated for professional use and over-the-counter sale. The Accu-Chek Compact system is indicated for lay person use with capillary whole blood samples drawn from the fingertips, forearm, upper arm, thigh, calf, and palm.
Test principle	**Step 1:** Glucose from the whole blood sample is oxidized by the PQQ-dependent enzyme glucose-dye-oxidoreductase to glucolactone 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. **Step 3:** The reduced form of the mediator reduces the indicator 2,18-phosphomolybdic acid to produce the color heteropolyblue.
Monitor	Designed for use with the currently distributed version of the Accu-Chek Compact meter.
Monitor coding procedure	Barcode containing coding information is printed on each drum of test strips.
Test strip storage conditions	Store at room temperature between +36° F (+2° C) and +86° F (+30° C).
Test strip operating conditions	Between +50° 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.

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6) Similarities (continued)

Feature/Claim	Detail
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.
Reagent stability	18 months
Reportable range	10-600 mg/dL
Hematocrit	20 - 65 %
Acceptable sample types	Professional Testing Capillary whole blood samples (fingertip or alternative sites) Venous whole blood samples Lay User Testing Capillary whole blood samples (fingertip or alternative sites)
Warnings and precautions	For *in vitro* diagnostic use only.
Reagent composition	• Glucose-dye-oxidoreductase * • Bis-(2-hydroxyethyl)-(4-hydroximinocyclohexa-2,5-dienylidene)-ammonium chloride • 2,18-phosphomolybdic acid • Stabilizer • Non-reactive ingredients *(*from A. Calcoaceticus, recombinant from E. Coli*)

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Differences

Feature	Accu-Chek Compact Test Strip (modified)	Accu-Chek Compact Test Strip (predicate)
Test time	8 seconds	15 seconds
Minimum sample volume	1.5 uL	3.5 uL
Interference from triglycerides	> 5000 mg/dL	> 1000 mg/dL
Bilirubin	None	> 20 mg/dL
Fluoride	Listed as interfering preservative in specimen collection section.	Listed as interfering preservative in specimen collection and limitations sections.
Accuracy	N = 120 Y=0.99x-1.96 Correlation coefficient = 0.983 Range = 56 - 531 mg/dL	N = 138 Y=0.954x+1.8 Correlation coefficient = 0.992 Range = 64 - 350 mg/dL
Consumer Studies	N = 120 Y=1.05x-5.065 Correlation coefficient = 0.983 Range = 56 - 531 mg/dL	N = 138 Y=0.956x+2.0 Correlation coefficient = 0.994 Range = 63 - 359 mg/dL
Precision, aqueous, low	N = 10 Mean = 43.2 mg/dL SD = 1.0	N = 10 Mean = 58.0 mg/dL SD = 1.0
Precision, aqueous, mid	None claimed	N = 10 Mean = 127.3 mg/dL %CV = 2.7
Precision, aqueous, high	N = 10 Mean = 339 mg/dL %CV = 1.5	N = 10 Mean = 227.7 %CV = 2.4
Precision, blood, low	N = 10 Mean = 36 mg/dL SD = 1.0	N = 20 Mean = 56 mg/dL SD = 1.4
Precision, blood, mid	N = 10 Mean = 165 mg/dL %CV = 1.4	N = 20 Mean = 140 mg/dL %CV = 1.9
Precision, blood, high	N = 10 Mean = 300 mg/dL %CV = 1.5	N = 20 Mean = 390 mg/dL %CV = 3.0

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7) Data demonstrating substantial equivalence	Performance testing on the modified Accu-Chek Compact Test Strip 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 clinical data demonstrates that the performance of the Accu-Chek Compact Test Strip correlates well with the laboratory plasma glucose reference test methodology. All predetermined acceptance criteria were satisfied. The data also demonstrates that the Accu-Chek Compact Test Strip is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Scott Thiel
Regulatory Affairs Specialist
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

JUL 0 3 2003

Re: k031755
Trade/Device Name: Accu-Chek Compact Test Strip
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW; LFR
Dated: June 3, 2003
Received: June 6, 2003

Dear Mr. Thiel:

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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
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): K03 1755 "Special"
Device Name: Accu-Chek Compact Test Strip

Indications for Use:

The Accu-Chek Compact Test Drums are used with the Accu-Chek Compact Meter. The Accu-Chek Compact system is designed to quantitatively measure the concentration of glucose in capillary and venous whole blood. The device is indicated for professional use and over-the-counter sale. The Accu-Chek Compact system is indicated for lay person use with capillary whole blood samples drawn from the fingertips, forearm, upper arm, thigh, calf, and palm.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031755

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

(Optional Format 1-2-96)