K081389

JUL 15 2008

ACCU-CHEK® Compact Plus Blood Glucose Monitoring System: 510(k) Summary

Sponsor

Roche Diagnostic
9115 Hague Road
Indianapolis, IN 46250 U.S.A.

Correspondent

Scott Thiel
Roche Diagnostic
9115 Hague Road
Indianapolis, IN 46250

Phone: (317)521-2000

Device Name and Classification

ACCU-CHEK® Compact Plus Blood Glucose Monitoring System

Common Name: glucose test system
Classification:

1. ACCU-CHEK Compact Plus Blood Glucose Meter and ACCU-CHEK Compact Test Strips are Class II devices (21 CFR § 862.1345)
2. ACCU-CHEK Compact Control Solutions are a Class I device (21 CFR § 862.1600)
3. ACCU-CHEK Softclix Lancing Device with ACCU-CHEK Softclix lancets are Class I (exempt) devices (21 CFR § 878.4800)

System Description

The ACCU-CHEK Compact Plus Blood Glucose Monitoring System consists of the ACCU-CHEK Compact Plus Meter, ACCU-CHEK Compact Test Strips (provided separately), ACCU-CHEK Compact Control Solutions (provided separately), ACCU-CHEK Softclix lancing device, and ACCU-CHEK Softclix lancets.

The ACCU-CHEK Compact Plus meter and ACCU-CHEK Softclix lancing device are modifications of the ACCU-CHEK Compact meter and ACCU-CHEK Softclix lancing device, respectively.

There are no changes to other system testing components compared to the currently marketed product.

Continued on next page

ACCU-CHEK® Compact Plus Blood Glucose Monitoring System: 510(k) Summary, Continued

Predicate Device	ACCU-CHEK Compact Blood Glucose Monitoring System.
Intended Use	The ACCU-CHEK Compact Test Drums are used with the ACCU-CHEK Compact or Compact Plus Meter. The ACCU-CHEK Compact and Compact Plus systems are designed to quantitatively measure the concentration of glucose in capillary and venous whole blood. The devices are indicated for professional use and over-the-counter sale. The ACCU-CHEK Compact and Compact Plus systems are indicated for lay use with capillary whole blood samples drawn from the fingertips, forearm, upper arm, thigh, calf, and palm.
Comparison to Predicate Device	The modifications to the device encompass: • Meter: ergonomic/physical design and electronic/hardware changes. • Lancing device: ergonomic/physical design • Control solution: color There have been no changes to the test strips, intended use, indications for use, operating principle, or functionality.
Technological Characteristics	There has been no change to the fundamental scientific technology.
Summary of Performance Characteristics	There has been no change to the performance characteristics of the system. A comparison of system accuracy performance demonstrated that the ACCU-CHEK Compact Plus system and the currently marketed ACCU-CHEK Compact system are substantially equivalent. The system maintains compliance with EN ISO 15197. Design verification testing confirmed that the performance, safety, and effectiveness of the ACCU-CHEK Compact Plus system are equivalent to the predicate device.
Conclusion	The ACCU-CHEK Compact Plus system is substantially equivalent to the predicate ACCU-CHEK Compact blood glucose monitoring system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Roche Diagnostics
c/o Mr. Scott Thiel
Regulatory Affairs Program Manager
9115 Hague Road
Indianapolis, IN 46256

JUL 15 2008

Re: k081389
Trade Name: ACCU-Chek Compact Plus Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Monitoring System
Regulatory Class: Class II
Product Codes: NBW, LFR
Dated: July 7, 2008
Received: July 8, 2008

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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k081389

Device Name: Accu-Chek Compact Plus Blood Glucose Monitoring System

Indication For Use:

The Accu-Chek Compact Test Drums are used with the Accu-Chek Compact or Compact Plus Meter. The Accu-Chek Compact and Compact Plus 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 and Compact Plus system are indicated for lay person use with capillary whole blood samples drawn from the fingertips, forearm, upper arm, thigh, calf, and palm.

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use __X__. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K081389