K983047

FEB 5 1999

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

Boehringer Mannheim Corporation
"doing business as Roche Diagnostics"
9115 Hague Rd.
Indianapolis, IN 46250
(800) 428-5074 ext. 3830

Contact Person: Mike Flis

Date Prepared: August 28, 1998

2) Device name

Proprietary name: Accu-Chek HQ System

Common name: Data processing module for clinical use

Classification name: Glucose test system

3) Predicate device

AccuData Glucose Test Station, FDA Control #K924475.

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510(k) Summary, Continued

4) Device Description

The Accu-Chek HQ system is a bedside data management unit that helps provide quality patient care by automating the record keeping associated with blood glucose and quality control tests. The Accu-Chek HQ system collects, stores, transfers information, and generates reports about the monitor, test strips, control solutions, patient results and operator performance for quality assurance.

This device is not intended to provide any diagnosis on patient results. The health care provider has the ability to visually confirm that the results on the Accu-Chek HQ display match the results on the monitor display. This inherent redundancy provides a method for the health care provider to confirm all data that is being logged by the Accu-Chek HQ system.

5) Intended use

The Accu-Chek HQ system is a bedside unit that can help health care professionals provide quality patient care by measurement of glucose on an Accu-Chek monitor, and by automating the record keeping associated with blood glucose and quality control tests.

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6) Comparison to predicate device

The Accu-Chek HQ System is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the Roche Diagnostics AccuData Glucose Test Station (GTS), FDA Control #K924475. The following table summarizes the similarities and difference between the new device and the predicate device.

Topic	Accu-Chek HQ (new device)	AccuData GTS (predicate device)
Used solely in conjunction with Accu-Chek blood glucose monitors	Yes	Yes
Intended use	The Accu-Chek HQ system is a bedside unit that can help you provide quality patient care by measurement of glucose on the Accu-Chek monitor, and by automating the record keeping associated with blood glucose and quality control tests.	The AccuData GTS is a bedside unit that can help you provide quality patient care by automating the record keeping associated with blood glucose and quality control tests.
Affect on blood glucose monitors' performance specifications	None	None
Affect on blood glucose test procedure (e.g., test strip insertion and dosing techniques)	None	None
Records	Time and date, operator ID, patient ID, proficiency sample ID, control solution information, test strip information, test results and comment codes.	Same
Connect directly to a printer to generate reports such as Levey-Jennings	Yes	Yes
Transfer information to another system for hospital-wide record keeping and data analysis	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 5 1999

Mr. Mike Flis
Regulatory Affairs Specialist
Boehringer Mannheim Corporation
9115 Hague Road
Indianapolis, Indiana 46250

Re: K983047
Trade Name: Accu-Chek HQ System
Regulatory Class: II
Product Code: LFR
Dated: December 14, 1998
Received: December 15, 1998

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

510(k) Number (if known): K983047
Device Name: Accu-Chek HQ System
Indications for Use:

The Accu-Chek HQ system is a bedside unit that can help health care professionals provide quality patient care by measurement of glucose on an Accu-Chek monitor, and by automating the record keeping associated with blood glucose and quality control tests.

(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 K983047

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

(Optional Format 1-2-96)