

K973662

Dec. 15, 1997

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
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: Mike Flis

Date Prepared:

2) Device name Proprietary name: Accu-Chek Complete Meter

Common name: Blood glucose test system

Classification name: glucose dehydrogenase, glucose

3) Predicate device We claim substantial equivalence to the Boehringer Mannheim Accu-Chek Advantage System. 510(k) files #k930979, #k951887, and #k954833.

4) Device Description The Accu-Chek Complete Meter is an invitro device designed for measuring the concentrations of glucose in whole blood which is applied to Accu-Chek Advantage or Accu-Chek Advantage H Test Strips.

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510(k) Summary, Continued

5) Intended use The Accu-Chek Complete System is designed for testing glucose by persons with diabetes or by health care professionals in the home or in health care facilities.

6) Comparison to predicate device The Boehringer Mannheim Accu-Chek Complete System is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Accu-Chek Advantage System.

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510(k) Summary, Continued

**Similarities to
Predicate
Device**

- Intended use [testing glucose in whole blood by persons with diabetes or by health care professionals in the home or health care facilities]
- Indicated for over-the-counter use with capillary blood samples only [Accu-Chek Advantage and Accu-Chek Advantage H Test Strips]
- Indicated for use with capillary, venous, arterial, and neonate blood samples by professionals (only applies to use with Accu-Chek H Test Strips) -- professional use with Accu-Chek Advantage Test Strips is limited to capillary blood samples
- Glucose dehydrogenase or glucose oxidase test strip (test principle) is unchanged - meter will operate with either strip version
- Meter operating procedure unchanged [The Advantage Test Strip employs the electrochemical principle of biamperometry. The monitor applies a voltage between two identical electrodes, the causes the reduced mediator formed during the test's incubation period to be reconverted to oxidized mediator. This generates a small current that is read by the meter.]
- Meter coding procedure unchanged
- Test strip dosing location remains outside the monitor -- meaning no strip guide or monitor optics cleaning required. Meter cleaning [Damp cloth of 10% bleach solution] and troubleshooting procedures unchanged.
- Meter storage condition limits unchanged [-13°F to 149°F, <95% RH]
- Meter operating condition limits unchanged [57°F to 104°F, <85% RH]
- Errors are depicted on LCD display and via audible beeps
- All test strip and liquid controls related directions for use and claims unchanged
- Limitations of procedure (including system measurement range) unchanged
- Expected results unchanged
- Instructions regarding response to unusual results unchanged
- Warnings and precautions unchanged
- Results referenced to whole blood laboratory testing unchanged

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Differences

Feature	Accu-Chek Advantage Meter (predicate)	Accu-Chek Complete (new device)
Fail-safe Mechanisms	<ul style="list-style-type: none"> • Out of temperature range • Out of reporting range • Erroneous strip insert • Memory Checksum • Calibration code error • Low battery voltage 	<ul style="list-style-type: none"> • Out of temperature range • Out of reporting range • Erroneous strip insert • Memory Checksum • Calibration code error • Low battery voltage • Serial Communication Error Detector
Calculations other than blood glucose test	None	Average, Minimum, and Maximum values for 2 days, 7 days, 14 days, 30 days
Meter size	91.4 x 50.8 x 15.2 mm	120.50 x 71.98 x 25.98 mm
Display viewing size	40.6 x 35.6 mm	52 x 34.7 mm
Weight	3 oz. with batteries	3.5 oz. without batteries
Power supply	Two 3-volt lithium coin cell batteries	Two AAA alkaline batteries
Data display	Numeric/Icon	Numeric/Icon/Graph
bG data stored in memory	mg/dl	mg/dl or mmol/l
Type of non-bG data stored	None	Carbohydrates, insulin, HbA1c, ketones, other indices
Memory capacity	100 blood glucose results with time and date	1000 data records
Data port	Multiplexed TTL UART	RS232
Buttons	2 "ON/OFF" and "MEM"	3 - multiple function corresponding to screen display
Turn On	Press "ON/OFF" button	Press any button or insert test strip



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 15 1997

Mike Flis
Regulatory Affairs Specialist
Boehringer Mannheim
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K973662
Accu-Chek® Complete™ System
Regulatory Class: II
Product Code: LFR, CGA
Dated: October 23, 1997
Received: October 24, 1997

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 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.

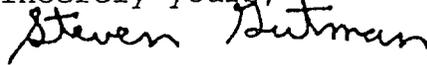
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/dsmamain.html>".

Sincerely yours,



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

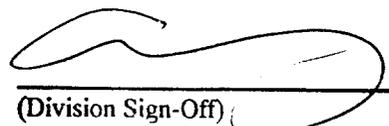
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510(k) Number (if known):
Device Name: Accu-Chek Complete System
Indications for Use:

The Accu-Chek Complete System is intended for testing glucose by persons with diabetes or by health care professionals in the home or in health care facilities.

(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 973662

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)