

Accu-Chek Advantage and Accu-Chek Advantage H Test Strips

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: June 5, 1998

2) Device name Proprietary name: Accu-Chek™ Advantage® and
Accu-Chek™ Advantage H™ Test Strips
Common name: Blood glucose test system
Classification name: glucose dehydrogenase, glucose

3) Predicate device We claim substantial equivalence to the unmodified Accu-Chek Advantage Test Strip.

4) Device Description The Accu-Chek Advantage and Accu-Chek Advantage H Test Strips are to be used with the Accu-Chek® Advantage® and Accu-Chek® Complete™ Monitors. The test strips are designed for convenient, confident, and accurate testing of blood glucose in whole blood samples.

Continued on next page

510(k) Summary, Continued

5) Intended use The Accu-Chek Advantage and Accu-Chek Advantage H Test Strips are to be used with the Accu-Chek® Advantage® and Accu-Chek® Complete™ Monitors. The Accu-Chek Advantage and Accu-Chek Complete monitors are designed for testing glucose in whole blood by persons with diabetes or by health care professionals in the home or in health care facilities.

Professionals may use the test strips to test capillary, venous, arterial and neonate (including cord) blood samples; lay use is limited to capillary blood testing.

6) Comparison to predicate device The modified Boehringer Mannheim Accu-Chek Advantage and Accu-Chek Advantage H Test Strips are 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 Test Strip (k951887 and k954833).

Blood glucose concentrations can be expressed two ways, as whole blood glucose or as plasma (or serum) glucose. The concentration of glucose in whole blood is lower (by about 8%) than the plasma glucose value for this same blood sample because of the differences in distribution of water between the two compartments (red blood cells and plasma). Test strips developed for the measurement of whole blood samples were traditionally referenced to provide a whole blood glucose value. However, many North American laboratories have, for the last few decades, routinely measured and reported only the plasma glucose values. Recent advancements in the management of patients with diabetes have created a preference to have the results for blood glucose test strips reflect the laboratory plasma value instead of the more traditional whole blood value. For this reason Boehringer Mannheim has modified the reference curve employed within the code key used with the Accu-Chek Advantage and Accu-Chek Advantage H test strips to now provide results which reflect the higher laboratory plasma glucose value.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 3 1998

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

Re: K982089
Accu-Chek® Advantage™ and Advantage H™ Test Strips
Regulatory Class: II
Product Code: LFR
Dated: June 11, 1998
Received: June 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 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.

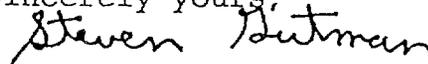
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

510(k) Number (if known):

Device Name: Accu-Chek™ Advantage® and Accu-Chek™ Advantage H™ Test Strips

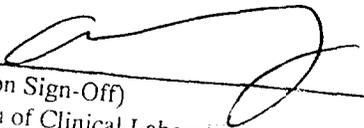
Indications for Use:

The Accu-Chek Advantage and Accu-Chek Advantage H Test Strips are to be used with the Accu-Chek® Advantage® and Accu-Chek® Complete™ Monitors. The Accu-Chek Advantage and Accu-Chek Complete monitors are designed for testing glucose in whole blood by persons with diabetes or by health care professionals in the home or in health care facilities.

Professionals may use the test strips to test capillary, venous, arterial and neonate (including cord) blood samples; lay use is limited to capillary blood testing.

(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 12982084

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)