

K974491

MAY 13 1998

## 510(k) Summary

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**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.

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**1) Submitter name, address, contact** Boehringer Mannheim Corporation  
9115 Hague Rd.  
Indianapolis, IN 46250  
(317) 845-2000

Contact Person: Mike Flis

Date Prepared: November 14, 1997

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**2) Device name** Proprietary name: Accu-Chek A<sub>1c</sub><sup>TM</sup> Hemoglobin Test

Common name: Hemoglobin A<sub>1c</sub> Test

Classification name: Glycosylated Hemoglobin Assay

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**3) Predicate device** The device is an accessory to our Tina Quant Hemoglobin A<sub>1c</sub> Assay. We claim our own device as the predicate device (#k934070).

In addition, a secondary predicate device may be considered. The role of the Accu-Chek A<sub>1c</sub> Hemoglobin Test in the overall process is substantially equivalent to the intended use of the Flexsite Diagnostics EZCHEK/HBA Blood Collection Kit (#k971919).

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**4) Device Description** The device is a kit containing the materials required to collect a whole blood sample on a test strip and mail it to a laboratory for determination of Hemoglobin A<sub>1c</sub>. The kit contains test strips, disposable lancets, instructions booklet, other related labeling, a return envelope, and a patient identification card for returning a result to the patient and/or his/her doctor.

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## 510(k) Summary, Continued

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**5) Intended use** The Accu-Chek A<sub>1c</sub> Hemoglobin Test is designed for use with BMC Hitachi reagents that measure glycosylated hemoglobin. The test has not been evaluated using any other methodology. The device is intended for at-home or in-office use to collect a whole blood sample. The product will be marketed over-the-counter. Our proposed labeling contains instructions for patients that test results should be evaluated together with a personal doctor.

Measurement of glycosylated hemoglobin is used to assess the level of control of a patient's diabetes and to determine the proper insulin dosage for a patient. Elevated levels of glycosylated hemoglobin indicate uncontrolled diabetes in a patient. This product is not indicated for the diagnosis of diabetes mellitus.

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**6) Comparison to predicate device** Use of the Accu-Chek A<sub>1c</sub> Hemoglobin Test with the Tina Quant assay only affects the pre-analytical stage of the testing process. All procedural steps and performance specifications associated with the analytical and post analytical stages of the assay are unaffected by the introduction of this accessory device.

The Tina Quant Hemoglobin A<sub>1c</sub> Test was evaluated for several performance characteristics, including precision and correlation. Additionally, the Accu-Chek A<sub>1c</sub> Hemoglobin Test was evaluated for reagent and sample stability when exposed to abusive environmental conditions. Actual use situations (user studies) were also performed. Study participants filled out questionnaires regarding the ease of use.

The evaluation studies provide evidence that results produced using samples collected by untrained lay persons using the accessory device correlate well with whole blood samples collected and handled directly by health care professionals following the procedure cleared in the original 510(k) file.

Study participants indicated that the kit is acceptable as designed.

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MAY 13 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

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

Re: K974491  
Accu-Chek A<sub>1c</sub><sup>TM</sup> Hemoglobin Test  
Regulatory Class: II  
Product Code: LCP  
Dated: March 27, 1998  
Received: March 30, 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.

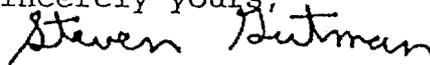
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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 A<sub>1c</sub><sup>TM</sup> Hemoglobin Test

Indications for Use:

The Accu-Chek A<sub>1c</sub><sup>TM</sup> Hemoglobin Test is designed for use with BMC Hitachi reagents that measure glycosylated hemoglobin. The test has not been evaluated using any other methodology. The device is intended for at-home or in-office use to collect a whole blood sample. The product will be marketed over-the-counter. Test results should be evaluated together with a personal doctor.

Measurement of glycosylated hemoglobin is used to assess the level of control of a patient's diabetes and to determine the proper insulin dosage for a patient. Elevated levels of glycosylated hemoglobin indicate uncontrolled diabetes in a patient. This product is not indicated for the diagnosis of diabetes mellitus.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Theronica J. Calver for A. W. Montgomery*

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K974491

Prescription Use ~~\_\_\_\_\_~~  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)