MAY 14 2009

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

A1CNow® for Home and Professional Use

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K090413

Prepared:	February 17, 2009
Submitter:	Bayer HealthCare Diabetes Care
Address:	510 Oakmead Parkway Sunnyvale, CA 94085 Phone (408) 524-2255; FAX (408) 524-2252
Contact:	Cathy Peters, Manager, Regulatory Affairs
Device:	Trade/Proprietary Names: A1CNow+ (Professional Use) A1CNow Self Check (Home Use)
Common/Usual Name:	Percent Hemoglobin A1c (percent glycosylated hemoglobin)
Classification:	Assay, Glycosylated Hemoglobin; 21 CFR 864.7470
Predicate Device:	A1cNow® Multi-Use for Home and Professional Use (InView™) K051321
Device Description:	The A1CNow+ tests provides quantitative measurement of the percent of glycated hemoglobin (%A1C) levels in capillary (fingerstick) or venous whole blood samples. The test is used to monitor glycemic control in people with diabetes. A1cNow+™ consists of 1) a semi-disposable plastic-encased device (the monitor), 2) a plastic cartridge enclosing dry reagent strips, and 3) a sample dilution kit for: collecting the blood sample, mixing the sample with the required pre-treatment solution, and delivering the sample to the cartridge. When testing with A1CNow+, an unmeasured whole blood mixture (diluted) is directly applied to the

	sample port, and the results are displayed in numeric form on the Monitor's liquid crystal display after 5 minutes.
Intended Use:	The A1CNow multi-use test provides quantitative measurement of the percent of glycated hemoglobin (%HbA1c, %A1C) levels in whole blood samples. The test is for home use and professional use for monitoring glycemic control in people with diabetes.
Technological Characteristics:	There were no changes to the intended use or fundamental scientific technology.
Comparison to Predicate device:	A1CNow is the same in fundamental technology and intended use to the predicate device, A1CNow, K051321, but has increased product stability and a simplified hemolysate preparation kit.
Assessment of Performance:	The performance was assessed in two separate clinical validation studies. The studies showed that changes to the hemolysate kit and product stability had no negative impact on product safety and efficacy. In addition, completed and ongoing product stability studies show no negative impacts of increased room temperature shelf life.
Conclusion:	The results of the verification and validation studies of A1CNow demonstrated that the product is safe and effective in the hands of lay users and healthcare professionals. The product is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 14 2009

Bayer HealthCare, LLC
c/o Ms. Cathy Peters
Regulatory Affairs Manager
510 Oakmead Parkway
Sunnyvale, CA 94085

Re: k090413
Trade/Device Name: A1CNow Self Check, A1CNow+
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP
Dated: April 14, 2009
Received: April 15, 2009

Dear Ms. Peters:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(K) Number (if known): K090413

Device Name: A1CNow+ (professional use), A1CNow Self Check (Home Use)

Indications for Use:
The A1CNow multi-use test provides quantitative measurement of the percent of glycated hemoglobin (%HbA1c, %A1C) levels in whole blood samples. The test is for home use and professional use for monitoring glycemic control in people with diabetes.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) **AND/OR** Over-The-Counter Use __X__ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K090413