



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-0609  
Silver Spring, MD 20993-0002

Bayer Healthcare  
c/o Marc Henn  
430 South Beiger Street  
Mishawaka, IN 46544

**AUG 26 2009**

Re: k091820

Trade/Device Name: Contour USB Blood Glucose Meter, Glucose Test Strips; Glucofacts  
Delux Diabetes Management System

Regulation Number: 21 CFR 862.1345

Regulation Name: Glucose test system.

Regulatory Class: II

Product Code: NBW, LFR, JQP

Dated: July 24, 2009

Received: July 29, 2009

Dear: Mr. Henn:

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.

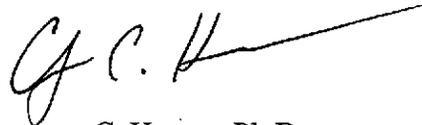
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

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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 (301) 796-5450. 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 (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 ( 301 ) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

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

## Indication for Use

510(k) Number (if known): K091820

Device Name: Contour USB, Glucofacts® DELUXE Diabetes Management Software

### Indication For Use:

The Contour USB Blood Glucose Monitoring System is used for the measurement of glucose in whole blood. The Contour USB is an over the counter (OTC) device utilized by persons with diabetes and by healthcare professionals in home settings and in healthcare facilities. The Contour USB Diabetes Care System is indicated for use with capillary, venous and arterial whole blood samples. Capillary samples may be drawn from fingertip, palm and forearm. The Contour USB is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. The frequent monitoring of blood glucose is an adjunct to the care of persons with diabetes.

GLUCOFACTS® Deluxe Diabetes Management Software is an over-the-counter software program intended for use by Health Care Professionals and Patients with Diabetes for viewing and printing reports that display blood sugar readings from Bayer's CONTOUR® and BREEZE® families of meters.

Prescription Use   X    
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use   X    
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

  
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Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K091820