Bayer HealthCare
Diabetes Care

MAR 1 2 2010

510(k) SUMMARY

DIDGET® World Reports Data Management Software

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 K093930

Prepared:	December 18, 2009
Submitter:	Bayer HealthCare Diabetes Care
Address:	777 Old Saw Mill River Road Tarrytown, NY 10591 Phone (914) 333-6736; FAX (914) 333-6160
Contact:	Susan Brocchi, Regulatory Affairs Specialist
Device:	Trade/Proprietary Name: DIDGET® World Reports Diabetes Management Software
Common/Usual Name:	Diabetes data management software program.
Classification:	Division of Clinical Laboratory Devices Panel – Clinical Chemistry and Toxicology Classification Code – 75 NBW, JQP
Predicate Device:	GLUCOFACTS® *Express* Diabetes Management Software, k082486
Device Description:	This software application allows the transfer of blood glucose results, along with time, date, and certain data markers, from Bayer's DIDGET® blood glucose meter to the DIDGET®World Reports web server through the use of a USB cable. Data analysis includes allowing the home-user or healthcare professional to view the data in five different ways: 1. Electronic logbook where all of the data can be seen 2. Glucose trend of the results by date 3. Daily blood glucose trend (standard day) 4. Weekly blood glucose trend (standard week) 5. Summary chart (histogram or pie chart)

Intended Use:	DIDGET® World Reports Diabetes Management Software is an over-the –counter software program for use by healthcare professionals and patients with diabetes for viewing and printing reports that display blood sugar readings from Bayer's DIDGET® blood glucose meter.
Technological Characteristics:	There were no changes to the fundamental scientific technology.
Comparison to Predicate device:	DIDGET® World Reports Diabetes Management Software is similar in function to the predicate device, GLUCOFACTS® *Express* Diabetes Management Software, k082486, but has been updated to run off of the Didget World web server.
Assessment of Performance:	Performance was assessed in a study that included fifty (50) subjects consisting of 3 healthcare professionals (HCPs) and 47 lay users (35 young adults with diabetes and 12 parents or legal guardians of children with diabetes). The study showed that the program is easy to use and the results are understandable by the users.
Conclusion:	The results of the verification and validation studies of the DIDGET® World Reports Diabetes Management Software demonstrated that the product is safe and effective in the hands of lay users and healthcare professionals. The product is substantially equivalent to the predicate device.

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 LLC
c/o Susan Brocchi
777 Old Saw Mill River Road,
Tarrytown, NY 10591

MAR 12 2010

Re: k093930
Trade/Device Name: DIDGET World Reports Diabetes Management Software
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: II
Product Code: NBW, JQP
Dated: February 17, 2010
Received: February 18, 2010

Dear Ms. Brocchi:

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).

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.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093930

Device Name: DIDGET® World Reports Diabetes Management Software

Indications for Use:

DIDGET® World Reports Diabetes Management Software is an over-the –counter software program for use by healthcare professionals and patients with diabetes for viewing and printing reports that display blood sugar readings from Bayer's DIDGET® blood glucose meter.

Prescription Use _____ And/Or Over the Counter Use _X_.
(21 CFR Part 801 Subpart D) (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)

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

510(k) K093930