K090628

DEC - 4 2009

Bayer HealthCare
Diabetes Care Division

510(k) Summary

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

The assigned 510(k) number is: K090628

Prepared:	November 30, 2009
Submitter:	Bayer Healthcare Diabetes Care
Address:	Bayer Healthcare, Diabetes Care 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 Common/Usual Name: Blood Glucose Meter
Classification:	Division of Clinical Laboratory Devices Panel – Clinical Chemistry and Toxicology Classification Regulation - 21CFR 862.1345 Product Code – 75 LFR (Glucose Dehydrogenase, Glucose)
Predicate Devices:	Contour Blood Glucose Meter (K062058, K060470)
Device Description:	The Didget Blood Glucose Monitoring System consists of: 1. Didget Blood Glucose Monitor 2. Contour Blood Glucose Test Strips 3. Contour Control Solution

Intended Use:	The Didget blood glucose monitoring system (meter, strips, and controls) is intended for self-testing by people with diabetes to monitor glucose concentrations in fresh capillary whole blood samples drawn from the fingertip only. It is intended for those ages four and older, with adult supervision as needed. The Didget blood glucose monitoring system is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.
Technological Characteristics:	There were no changes to the fundamental scientific technology
Comparison to Predicate Device:	The modifications to the device encompass meter size/shape design changes. There has been no change to the operating principle. An interface for a Nintendo gaming system was added. The indication was modified.
Assessment of Performance:	An evaluation of the Didget Blood Glucose Monitoring System was studied in the laboratory and in a clinical setting using persons with diabetes, ages 5 through 24. The results were compared to results from the currently marketed Contour system and to a laboratory method. The studies showed equivalent performance with the current Contour system.
Conclusion:	The results of clinical evaluations of the Didget Blood Glucose Monitoring System demonstrated that the device can produce blood glucose results that are substantially equivalent to results obtained on 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

DEC 4 2009

Bayer HealthCare Diabetes Care
c/o Ms. Susan Brocchi
Regulatory Affairs Specialist
777 Old Saw Mill River Road
Tarrytown, NY 10591

Re: k090628
Trade Name: Didget Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: NBW, LFR, JJX
Dated: November 03, 2009
Received: November 04, 2009

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

Indication for Use

510(k) Number (if known): 090628

Device Name: Didget

Indication for Use:

The Didget blood glucose monitoring system (meter, strips, and controls) is intended for self-testing by people with diabetes to monitor glucose concentrations in fresh capillary whole blood samples drawn from the fingertip only. It is intended for those ages four and older, with adult supervision as needed. The Didget blood glucose monitoring system is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

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)

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

510(k) K090628