K090609

Okbiotech
訊映光電股份有限公司
Taiwan : TEL : 886-3-5160258 FAX : 886-3-5160028
China : TEL : 86-791-3899362 FAX : 86-791-3880131
http://www.okbiotech.com
E-mail:service@okbiotech.com

FEB - 4 2010

II. 510(K) Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

2.1. General Information Establishment

- Manufacturer: **OK Biotech Co., Ltd.**
- Address: 1F, No. 87, Sec. 2, Gongdaowu Road, Hsin Chu City, 30070, Taiwan. ROC
- Owner Number: **9090860**
- Contact Person: Dr. Jen, Ke-Min E-mail: ccirs.jen@msa.hinet.net
  886-3-5208829 (Tel); 886-3-5209783 (Fax)
  Address: No.58, Fu Chiun Street, Hsin Chu City, 30067, Taiwan. ROC
- Date Prepared: February 27, 2009

Device

- **Proprietary Name:** *Okmeter Match Blood Glucose Monitoring System*
- **Common Name:** Blood Glucose Monitoring System
- **Classification Name:** SYSTEM, TEST, BLOOD GLUCOSE, OVER THE COUNTER, Class II
- **Product Code:** NBW

2.2. Safety and Effectiveness Information

- **Predicate Device:**
  Claim of Substantial Equivalence (SE) is made to *PRODIGY Voice Blood Glucose Monitoring System* **(K073118)**
- **Device Description:** Based on an electrochemical biosensor technology and the principle of capillary action, *Okmeter Match Blood Glucose Monitoring System* only needs a small amount of blood. Capillary action at the end of the test strip draws the blood into the action chamber and your blood glucose result is precisely and displayed in 6 seconds. The device including two test strips there are identical in structure design and test performance, the only difference in colors (White for strip A and Green for strip B).
- **Intended Use:**
  The Okmeter Match Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. The alternative

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site testing in this system can be used only during steady-state blood glucose conditions. The meter has some audible features but it is not for use by the visually impaired.

The Okmeter Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. Okmeter Test Strips must be used with the Okmeter Match Blood Glucose Monitoring System. Testing is done outside the body (In Vitro diagnostic use). They are indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. They are not intended for the diagnosis of or screening for diabetes mellitus, and are not intended for use on neonates.

The Okmeter 2 levels (Normal and High) Control Solution are for use with the Okmeter Match Blood Glucose Monitoring System and Okmeter Test Strips as a quality control check to verify the accuracy of blood glucose test results.

- **Synopsis of Test Methods and Results**

  Pre-clinical and clinical data are employed upon submission of this 510(K) premarket notification according to the *Guidance Document for In Vitro Diagnostic Test System; Guidance for Industry and FDA* document provided by CDRH/ FDA.

- **Substantial Equivalence (SE)**

  A claim of substantial equivalence is made to *PRODIGY Voice Blood Glucose Monitoring System* **(K073118).** Both of them have the same working principle and technologies including sample volume, measuring time, detecting range, HCT range, calibration method, voice function, and memory data number. The major differences for the two devices are meter dimension, weight; and the subject has two test strips. Besides, the subject device and predicate device is same intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. Thus the differences are due to the feature design aspects, not relating to the safety or effectiveness aspects. They are substantially equivalent.

Dr. Jen, Ke-Min
official correspondent for
OK BIOTECH CO., LTD.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

FEB - 4 2010

OK Biotech Co., Ltd.
c/o Dr. Ke-Min Jen
ROC Chinese-European Indus. Research Society
No. 58, Fu Chuin Street
Hsin Chu City, China (Taiwan) 30067

Re: k090609
Trade Name: OKmeter Match Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: January 19, 2010
Received: January 19, 2010

Dear Dr. Ke-Min Jen:

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): K090609

Device Name: *Okmeter Match Blood Glucose Monitoring System*

Indication For Use:

The Okmeter Match Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. The alternative site testing in this system can be used only during steady-state blood glucose conditions. The meter has some audible features but it is not for use by the visually impaired.

The Okmeter Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. Okmeter Test Strips must be used with the Okmeter Match Blood Glucose Monitoring System. Testing is done outside the body (In Vitro diagnostic use). They are indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. They are not intended for the diagnosis of or screening for diabetes mellitus, and are not intended for use on neonates.

The Okmeter 2 levels (Normal and High) Control Solution are for use with the Okmeter Match Blood Glucose Monitoring System and Okmeter Test Strips as a quality control check to verify the accuracy of blood glucose test results.

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

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K090609