K112653

APR - 9 2012

5. 510(k) SUMMARY

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 _ _____.

Submitter's Identification:

ACON Laboratories, Inc.

10125 Mesa Rim Road

San Diego, California 92121

Tel.: 858-875-8019
Fax: 858-875-8099

Date Prepared: May 14, 2011

Contact Person:

Qiyi Xie
Senior Staff, Clinical & Regulatory Affairs

Proprietary Name of the Device:

On Call® Vivid Blood Glucose Monitoring System

Common Name:

Glucose Test System

Classification Name:

Class II §862.1345 Glucose Test System

Predicate Device:

One Touch Ultra Blood Glucose Monitoring System
Lifescan, Inc., located at 1000 Gibraltar Dr., Milpitas, CA 95035, USA.
510(k) Number: K002134

Device Name: On Call® Vivid Blood Glucose Monitoring System

Proprietary Name	Classification	Product Code	Description	Common Name
On Call® Vivid Blood Glucose Monitoring System	862.1345 Class II	75 NBW	System, Test, Blood Glucose, Over The Counter	Glucose Test System
On Call® Vivid Blood Glucose Meter and On Call® Vivid Blood Glucose Test Strips	862.1345 Class II	75 CGA	Glucose Monitor	Glucose Meter & Test Strips
On Call® Vivid Glucose Control Solution	862.1660 Class I	75 JJX	Single Analyte Control	Control Solution
On Call® Lancets and On Call® Lancing Device	878.4800 Class I	79 FMK	Lancet, Blood	Lancets

Description:

The On Call® Vivid Blood Glucose Monitoring System is a quantitative assay for the detection of glucose in capillary whole blood sampled from the fingertip, palm, and forearm. The glucose measurement is achieved by using the amperometric detection method.

The test strip has a reagent system including glucose oxidase and a mediator that reacts with glucose in the whole blood sample to produce an electrical current. This current is measured by the meter, and after calculation by the meter, the blood glucose concentration reading is displayed on the meter display, calibrated to a plasma reference.

Intended Use:

The On Call® Vivid Blood Glucose Monitoring System is an electrochemical enzymatic assay for the quantitative detection of glucose in fresh capillary whole blood from the fingertip, forearm, and palm by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control programs. Fingertip, forearm and palm testing sites should be used alternately only when blood glucose level is not changing rapidly. The On Call® Vivid Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. It is for in vitro diagnostic use only.

- This device is not indicated for the diagnosis or screening of diabetes.
- Alternative site testing can be used only during steady-state blood glucose conditions.
- Alternative site testing (AST) should not be used to calibrate continuous glucose monitors (CGMs) nor for use in insulin dose calculations.
- The On Call Vivid Blood Glucose Meter and Strips are to be used with the On Call Vivid Blood Glucose Monitoring System; it measures glucose in capillary whole blood from the fingertip, forearm and palm.
- For In Vitro Diagnostic Use

Technological Characteristics:

Specification of Blood Glucose Meter:

Feature	Specification
Measurement Range	20 to 600 mg/dL (1.1-33.3 mmol/L)
Result Calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Minimum Sample Size	0.8 µL
Test Time	5 seconds
Power Source	Two (2) CR 2032 3.0V coin cell batteries
Battery Life	Minimum of 3,000 measurements (without considering data transfer and test reminder alarms)
Glucose Units of Measure	The meter is pre-set at time of manufacturing to either millimoles per liter (mmol/L) or milligrams per deciliter (mg/dL) depending on the standard of your country. The meter will be set to mg/dL by default when sold in the United States.
Memory	Up to 300 records with time and date
Meter Size	3.58" x 2.28" x 0.83"
Display Size	1.58" x 1.42"
Weight	Approximately 60 g (without battery installed)
Operating Temperature	5-45°C (41-113°F)
Operating RelativeHumidity	10-90% (non-condensing)
Hematocrit Range	20-70%
Data Port	9600 baud, 8 data bits, 1 stop bit, no parity

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Acon Laboratories, Inc.
c/o Qiyi Xie
10125 Mesa Rim Rd.
San Diego, CA 92121

APR - 9 2012

Re: k112653
Trade Name: On Call Vivid Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: II
Product Code: CGA, NBW, JJX
Dated: March 17, 2012
Received: March 19, 2012

Dear Dr. Xie:

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K112653

Device Name: On Call® Vivid Blood Glucose Monitoring System

The On Call® Vivid Blood Glucose Monitoring System is an electrochemical enzymatic assay for the quantitative detection of glucose in fresh capillary whole blood from the fingertip, forearm, and palm by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control programs. Alternate testing sites (forearm and palm) should be used only during steady-state times (when blood glucose level is not changing rapidly). The On Call® Vivid Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients. It is for in vitro diagnostic use only.

The On Call® Vivid Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes mellitus or for neonatal use.

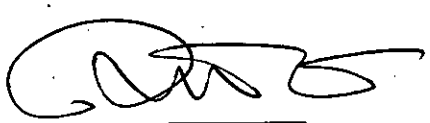
The On Call® Vivid Blood Glucose Test Strips are used with the On Call Vivid Blood Glucose Meter in the quantitative measurement of glucose in fresh capillary blood from the fingertip, forearm, and palm.

The On Call® Vivid Blood Glucose Control Solution is for use with the On Call® Vivid Blood Glucose Meter and Test Strips as a quality control check to verify that the meter and test strips are working together properly and that the test is performing correctly.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-off
Office of In Vitro Diagnostic Devices
Evaluation and Safety

510(k) K112653