K110435

SEP 21 2011

510(k) SUMMARY

(As required by 21.CFR.807.92)

Introduction: According to the requirements of 21 CFR.807.92, the following information provides sufficient data to understand the basis for a determination of substantial equivalence.

Submitted By: US Diagnostics, Inc.
304 Park Avenue South
Suite 218
New York, NY 10010

Contact Person: Jonathan Johnson
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Fax: 800-931-9137

Date Summary, Prepared: September 8, 2011

Device Name: Propriety Name: EasyGluco® Plus Blood Glucose Monitoring System
Common Name: Blood Glucose Test System
Classification Name: Class II, 862.1345 Blood Glucose Monitoring System

Predicate Device: We claim substantial equivalence to the G5 Infinity Blood Glucose Monitoring System, K082201.

Device Description: The EasyGluco® Plus Monitor is an in vitro diagnostic device designed for measuring the concentration of glucose in whole blood, which is used with the EasyGluco® Plus Test Strips.

The test principle is:

This device is an in vitro diagnostic product intended for the measurement of glucose concentration in human blood. The principle of the test relies upon a specific type of glucose in the blood sample, the dehydrogenase glucose that reacts to electrodes in the test strip. The test strip employs an electrochemical signal generating an electrical current that will stimulate a chemical reaction. This reaction is measured by the Meter and displayed as your blood glucose result.

Intended Use: The EasyGluco® Plus Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf or thigh as an aid in monitoring the effectiveness of

diabetes management in the home by patients with diabetes. The EasyGluco® Plus Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared with any other person.

EasyGluco® Plus System is for self testing outside the body (in vitro diagnostic use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The EasyGluco® Plus Blood Glucose Monitoring System should not be used for the diagnosis or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The EasyGluco® Plus Blood Glucose Test Strips are for use with the EasyGluco® Plus Blood Glucose Monitor for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf or thigh.

Comparison to Predicate Device: The US Diagnostics, Inc. EasyGluco® Plus Module is substantially equivalent to the other products in commercial distribution intended for similar use. The most notable, it is substantially equivalent to the currently marketed item, K082201-G5 Infinity Blood Glucose Monitoring System.

Conclusion: The EasyGluco® Plus Blood Glucose Monitoring System is substantially equivalent to the following predicate devices:
K082201-G5 Infinity Blood Glucose Monitoring System

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

US Diagnostics
c/o Jonathan Johnson
304 Park Ave South
Suite 218
New York, NY, 10010, US

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

SEP 21 2011

Re: k110435
Trade Name: EasyGluco Plus Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: August 22, 2011
Received: August 26, 2011

Dear Mr. Johnson:

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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 110435

Device Name: EasyGluco® Plus Blood Glucose Monitoring System

Indication for Use:

The EasyGluco® Plus Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf or thigh as an aid in monitoring the effectiveness of diabetes management in the home by patients with diabetes. The EasyGluco® Plus Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared with any other person.

EasyGluco® Plus System is for self testing outside the body (in vitro diagnostic use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The EasyGluco® Plus Blood Glucose Monitoring System should not be used for the diagnosis or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

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Prescription Use __X__	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

K110435