

K082201

**510(k) SUMMARY**  
(As required by 21.CFR.807.92)

FEB 20 2009

**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:** Edward Letko  
Phone: 917-402-5900  
Fax: 212-202-5173

**Date Summary,  
Prepared:** February 5, 2009

**Device Name:** Propriety Name: G5 Infinity™  
Common Name: Blood Glucose Test System  
Classification Name: Class II, 862.1345 Glucose Blood Tester

**Predicate Device:** We claim substantial equivalence to the LifeScan, Inc., OneTouch® Ultra®.

**Device**

**Description:** The Infinity™ Monitor is an in vitro diagnostic device designed for measuring the concentration of glucose in whole blood, which is used with the Infinity™ 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 Infinity™ Meter device is used along with the Infinity™ Test Strips is used for the quantitative measurement of glucose level in whole blood as an aid in monitoring the effectiveness of diabetes management in the home and in clinical settings. Infinity™ System is for testing outside the body (in vitro diagnostic use only). Testing sites include the traditional fingertip testing along with alternate site testing on the dorsal palm, ventral palm, forearm, upper arm, calf and thigh.

## **510(k) Summary, Continued**

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giving it an attractive, nearly painless alternative to the more painful fingertip site.

**Comparison to  
Predicate Device:**

The US Diagnostics, Inc. Infinity™ 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, the OneTouch® Ultra® by LifeScan, Inc.

**Conclusion:**

The Infinity™ Blood Glucose Monitoring System is substantially equivalent to the following predicate devices:  
K024194 – LifeScan, Inc. OneTouch® Ultra®  
K984261 – LifeScan, Inc. SURESTEP®  
K021513 – Roche Diagnostics Corp. Accu-Chek Advantage



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

U.S. Diagnostics, Inc.  
c/o Jonathan Johnson  
304 Park Avenue South  
Suite 218  
New York, NY 10010-4301

FEB 20 2009

Re: k082201  
Trade Name: G5 Infinity Blood Glucose Monitoring System  
Regulation Number: 21 CFR 862.1345  
Regulation Name: Blood Glucose Test System, Glucose Oxidase  
Regulatory Class: Class II  
Product Codes: NBW, CGA, JJX  
Dated: February 9, 2009  
Received: February 10, 2009

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.

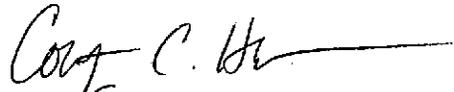
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Courtney C. Harper, Ph.D.  
Acting Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

## Indication for Use

510(k) Number (if known): K082201

Device Name: G5 Infinity™ Blood Glucose Monitoring System

Indication For Use:

The G5 Infinity™ Meter device is used along with the G5 Infinity™ Test Strips for the quantitative measurement of glucose level in whole blood as an aid in monitoring the effectiveness of diabetes management in the home by patients with diabetes and in clinical settings by healthcare professionals. G5 Infinity™ System is for testing outside the body (in vitro diagnostic use only). Testing sites include the traditional fingertip testing along with alternate site testing on the dorsal palm, ventral palm, forearm, upper arm, calf and thigh. The G5 Infinity™ Blood Glucose Monitoring System is not intended for screening or diagnosis of diabetes and also not for use with 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

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