510(k) Summary

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

1. Submitter Name, Address, Contact

All Medicus., Co. Ltd.
#7608, Dong-il Techno Town 7th.,
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Contact Person : Ms. Margaret Kim

FEB 27 2009

2. Date Prepared

May, 2008

3. Device Name

Propriety name : GlucoDr™ Plus System
Common name : Blood glucose monitoring system
Classification name : Glucose Test System Class II
(21 CFR Section 862.1345, Product Code : LFR, NBW)
Quality control material Class I
(21 CFR Section 862.1660, Product Code : JJX)

4. Predicate Device

We claim substantial equivalence to the Roche Diagnostics Corporation, Accu-Chek Aviva System. (K043474)

5. Device Description

The GlucoDr™ Plus system consists of GlucoDr™ Plus Test Meter, GlucoDr™ Plus Test strips and GlucoDr™ Plus control solution.

The GlucoDr™ Plus system is based on measurement of electrical currents caused by the reaction of glucose with reagents on the gold electrode strip. Glucose in the sample reacts with glucose dehydrogenase and mediators. This reaction creates electrical currents. The subsequent electrical currents are proportional to the glucose concentration in the blood and converted to the equivalent glucose concentration by the algorithm programmed in the GlucoDr™ Plus test meter.

6. Intended use

The GlucoDr™ Plus system is intended for in vitro diagnostic use (i.e., for external use only) for quantitative measurement of glucose in venous whole blood and capillary whole blood. Testing sites include traditional fingertip site along with palm, arm and thigh.

The GlucoDr™ Plus system may be used by healthcare professionals or for self testing by diabetic lay users with diabetes mellitus at home as aid in monitoring the effectiveness of diabetes control program.

The GlucoDr™ Plus system is not intended for the diagnosis of or screening for diabetes mellitus, nor intended for use on neonates.

The GlucoDr™ Plus control solution is for use with the The GlucoDr™ Plus meters and strips as a quality control check to verify the accuracy of blood glucose test results.

7. Comparison to Predicate Device

The GlucoDr™ Plus system has equivalent technological characteristics as the Accu-Chek Aviva System. The GlucoDr™ Plus system also has the same intended use as the Accu-Chek Aviva System.

8. Conclusion

The GlucoDr™ Plus system is substantially equivalent to the predicate device system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

All Medicus Co., Ltd.
c/o Ms. Margaret Kim
Regional Manager
No. 7608 Dong-il Techno Town 7TH
823 Gwanyang 2-dong, Dongan-gu
Anyang, Gyeonggi-do
Republic of Korea 431-062

FEB 27 2009

Re: k082328
Trade/Device Name: GlucoDr™ Plus System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, LFR and JJX
Dated: January 16, 2009
Received: January 16, 2009

Dear Ms. Kim:

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): K082328

Device Name: **GlucoDr™ Plus System**

Indication For Use:

The GlucoDr™ Plus system is intended for in vitro diagnostic use (i.e., for external use only) for quantitative measurement of glucose in venous whole blood and capillary whole blood. Testing sites include traditional fingertip site along with palm, arm and thigh.

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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) K082328