K140141

JUL 0 3 2014

510(k) Summary

In accordance with the requirements of 21 CFR.807.92, the following information about 510(k) safety and effectiveness is being submitted.

1. Submitter

CERAGEM Medisys Inc.
16, Jeongjal-gil, Seonggeo-eup, Seobuk-gu,
Cheonan-si, Chungcheongnam-do, 331-833, Republic of Korea
Phone : (82) 41-529-8427
Fax : (82) 41-551-0767
Contact Person: Dana Moon

2. Date Prepared

July 3, 2014

3. Device Name

Common name : LabonaCheck® Gluppy Blood Glucose Monitoring System
Classification : Class II
(Regulation: 21 CFR § 862.1345)
Product Code : NBW, CGA(Blood Glucose Test System, Over the Count)

4. Predicate Device

The difference between Predicate device (k102751) and Candidate device is shape of the test strip,Coding and Manufacturer Address. The rest of the device is substantially equivalent to existing device described as below.

(1) Device Name: LabonaCheck® Gluppy Blood Glucose Monitoring System
(2) Model: MG 200
(3) Manufacturer: CERAGEM Medisys Inc.
(4) 510(K) Number: K102751

5. Device Description

The system consists of Test Meter, Test Strips, Lancing Device, lancets, 3V battery and Carrying Case.

The system measures the amount of glucose (sugar) in whole blood. Blood is applied to the absorbent hole of the test strip and automatically drawn into the reaction zone where reaction between reagent and glucose occurs.

6. Indication for use

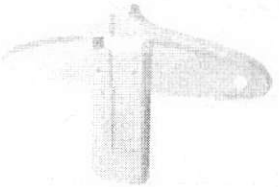
The LabonaCheck® Gluppy Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip. The LabonaCheck® Gluppy Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The LabonaCheck® Gluppy Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The LabonaCheck® Gluppy Blood Glucose Monitoring System should not be used for the diagnosis or screening of diabetes or for neonatal use.

The LabonaCheck® Gluppy Blood Glucose Test Strips are for use with the LabonaCheck® Gluppy Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip.

7. Comparison with predicate

Comparison		
Item	**Candidate Device**	**Predicate (k102751)**
Device Name	LabonaCheck® Gluppy	LabonaCheck® Gluppy (existing device)
Similarities		
Indications for Use	Same	Quantitative measurement of glucose in capillary whole blood
Testing Site	Same	Fingertip only
Detection Method	Same	Amperometry
Enzyme	Same	Glucose Oxidase

Mediator	Same	Potassium ferricyanide
Test range	Same	20~600 mg/dL
Temperature range	Same	50~104°F 10~40°C
Sample Volume	Same	1.0 uL
Operating Humidity range	Same	10- 80%
Electrode	Same	Noble metal electrode
Warranty (Test Meter)	Same	3 years
Power(Battery)	Same	CR2032
Open use time (Test Strips)	Same	4 months
Reaction Time	Same	5 second
Hematocrit range	Same	20~60%
Interference	Same	Uric acid > 8.0mg/dL Triglycerides > 400 mg/dL Sodium fluoride > 500mg/dL
Memory	Same	500 results with date and time
Performance Characteristics	Same	Refer to N. Performance Characteristics on 6 page
Differences		
Coding	No code	Code key required
Shape of the test strip		

Manufacturer Address	103-703, Sk Ventium, 522 Dangjeong-dong, Gunpo-si, 435-77, Korea	16, Jeongja 1-gil,Seonggeo-eup, Seobuk-gu, Cheonan-si, Chungcheongnam-do, 331-833, Korea

Conclusion

As the comparison table, Both of Candidate and predicate device have same test site, detection method, test range, temperature range, sample volume, operating humidity range, electrode, warranty, power, open use time, reaction time, hematocrit range, interference, memory, and performance characteristics. Furthermore Candidate Device is also using enzyme and mediator. To sum up with the similarities, candidate device is similar with the predicate device because most of the specifications deciding the characteristic of the device are same. Only the shape of the test strip and manufacturer address has been changed. In conclusion, despite of the difference such as mentioned above, the LabonaCheck® Gluppy Blood Glucose Monitoring System is substantially equivalent as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 3, 2014

CERAGEM MEDISYS INC.
DANA MOON
16 JEONGIAL-GIL, SEONGGEO-EUP, SEOBUK-GU
CHEONAN, CHUNGCHEONGNAM-DO 331-833
KOREA

Re: K140141
Trade/Device Name: LabonaCheck® Gluppy Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA
Dated: June 05, 2014
Received: June 16, 2014

Dear Dana Moon:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k140141

Device Name
LabonaCheck® Gluppy Blood Glucose Monitoring System

Indications for Use *(Describe)*
The LabonaCheck® Gluppy Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The LabonaCheck® Gluppy Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The LabonaCheck® Gluppy Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes controls. The LabonaCheck® Gluppy Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The LabonaCheck® Gluppy Blood Glucose Test Strips are for use with the LabonaCheck® Gluppy Blood Glucose Test Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Stayce Beck -S

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