DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 30, 2014

CERAGEM MEDISYS INC.
HAK-SUNG KIM
16 JEONGJA1-GIL, SEONGGEO-EUP, SEOBUK-GU, CHEONAN-SI,
CHUNGCHEONGNAM-DO, 331-833
KOREA

Re: K141829
Trade/Device Name: GlucoVitaal H1A Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, LFR, JJX
Dated: September 24, 2014
Received: September 24, 2014

Dear Mr. Hak-Sung Kim:

This letter corrects our substantially equivalent letter of September 24, 2014.

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 regulation (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" (21CFR 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

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)*
k141829

Device Name

GlucoVitaal H1A Blood Glucose Monitoring System

Indications for Use *(Describe)*

The GlucoVitaal H1A 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, forearm, upper arm, palm, thigh, or calf. The GlucoVitaal H1A Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The GlucoVitaal H1A 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 GlucoVitaal H1A Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GlucoVitaal H1A Blood Glucose Test Strips are for use with the GlucoVitaal H1A Blood Glucose Test Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, forearm, upper arm, palm, thigh, or calf.

The GlucoVitaal H1A Glucose Control Solution is for use with the GlucoVitaal H1A Blood Glucose Test 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.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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.
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Cheonan-si, Chungcheongnam-do, 331-833, Republic of Korea
Phone : (+82) 41-529-8422
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Contact Person: Hak-Sung Kim

2. Date Prepared

September 24, 2014

3. Device Name

Common name : GlucoVitaal H1A Blood Glucose Monitoring System
Classification : Class II
(Regulation: 21 CFR § 862.1345)
Product Code :
NBW – Blood glucose test system, over the count
LFR - Glucose, Glucose dehydrogenase, glucose test system
JJX, Single (specified) analyte controls

4. Predicate Device

The difference between Predicate device (k131727) and Candidate device is name of test system, code setting and adding languages (Spanish and Portuguese) on the labeling.

The name of k131727 test system is CERA-CHEK 1070 Blood Glucose Monitoring System, while candidate device is GlucoVitaal H1A Blood Glucose Monitoring System.

Regarding the code setting, predicate device can select the coding the built-in code in meter. On the contrary, candidate device is no need to set coding because only one setting code was built-in the meter. Both of them are identical including electrode, contact port size and reactants in test strip. Therefore modification of code setting is no effect on the performance test.

For further information, see table below for references:

Table1. Difference

	Predicate Device (k131727)	Candidate Device
Name of System device	CERA-CHEK 1070 Blood Glucose Monitoring System	GlucoVitaal Blood Glucose Monitoring System
Code Setting	Code key required	No code
Language	Only English	English, Spanish and Portuguese

GlucoVitaal H1A Blood Glucose Monitoring System is substantially equivalent to CERA-CHEK 1070 Blood Glucose Monitoring System described as below.

(1) Device Name: CERA-CHEK 1070 Blood Glucose Monitoring System
(2) Manufacturer: CERAGEM Medisys Inc.
(3) 510(K) Number: k131727

5. Device Description

The GlucoVitaal H1A Blood Glucose Monitoring System consists of GlucoVitaal H1A Blood Glucose Test Meter, GlucoVitaal H1A Blood Glucose Test Strips, GlucoVitaal H1A Glucose Control Solution 1 and Control Solution 2, a Lancing device. Control Solution 1 and Control Solution 2 are required but not included with the meter. Control Solution 1 and Control Solution 2 are always provided as a set.

6. Intended Use

The GlucoVitaal H1A 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, forearm, upper arm, palm, thigh, or calf. The GlucoVitaal H1A Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The GlucoVitaal H1A 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 GlucoVitaal H1A Blood Glucose Monitoring System should not be used for the diagnosis of 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 GlucoVitaal H1A Blood Glucose Test Strips are for use with the GlucoVitaal H1A Blood Glucose Test Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, forearm, upper arm, palm, thigh, or calf.

The GlucoVitaal H1A Glucose Control Solution is for use with the GlucoVitaal H1A Blood Glucose Test 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.

7. Comparison to Predicate Device

Table2. Comparison Table

Comparison		
Item	**Predicate Device (k131727)**	**Candidate Device**
Device Name	CERA-CHEK 1070 Blood Glucose Monitoring System	GlucoVitaal H1A Blood Glucose Monitoring System
Same		
Detection Method	Amperometry	Amperometry
Enzyme	Glucose dehydrogenase (FAD-GDH)	Glucose dehydrogenase (FAD-GDH)
Test Time	5 seconds	5 seconds
Memory	1000 blood glucose test results with date and time	1000 blood glucose test results with date and time
Sample Volume	0.5 uL	0.5 uL
Humidity range	10-85%	10-85%
Temperature range	50-104°F 10-40°C	50-104°F 10-40°C
Power(Battery)	One 3-volt lithium battery (CR2032)	One 3-volt lithium battery (CR2032)
Test range	20-600 mg/dL	20-600 mg/dL
Level of QC	2 Levels (Control 1, Control 2)	2 Levels (Control 1, Control 2)
Dimensions	94mm(H) x 53.6(W) x 14.9mm(T)	94mm(H) x 53.6(W) x 14.9mm(T)
Weight	35g	35g

Hematocrit range	10-70%	10-70%
Difference		
Name of System device	CERA-CHEK 1070 Blood Glucose Monitoring System	GlucoVitaal Blood Glucose Monitoring System
Code Setting	Code key required	No code
Language	Only English	English, Spanish and Portuguese

Conclusion

As the comparison table, both of Candidate and Predicate device have same detection method, test time, memory, sample volume, Humidity range, temperature range, battery, test range, level of QC, dimensions, weight and hematocrit range. Furthermore Candidate device is also using same enzyme and mediator. To sum up with table, the GlucoVitaal H1A Blood Glucose Monitoring System (candidate device) is similar with the predicate device because most of the specifications deciding the characteristic of the device are same. In conclusion, despite of the difference such as mentioned above, the GlucoVitaal H1A Blood Glucose Monitoring System is substantially equivalent as compared to the predicate device.