March 26, 2020

Jana Care, Inc.
% Fran White
President
MDC Associates, Inc.
180 Cabot St
Beverly, MA 01915

Re: K192987
Trade/Device Name: Aina HbA1c Monitoring System 2
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated Hemoglobin Assay
Regulatory Class: Class II
Product Code: LCP
Dated: February 20, 2020
Received: February 21, 2020

Dear Fran White:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Acting Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k192987

Device Name
Aina HbA1c Monitoring System 2

Indications for Use *(Describe)*

The Aina HbA1c Monitoring System 2 consists of the Aina 2 Automated HbA1c Device, the Aina Device, Aina HbA1c Test Kits, mobile device, and the Aina Mobile Application. It is intended to be used for quantitative measurement of %HbA1c (DCCT/NGSP) and mmol/mol HbA1c (IFCC) in human anticoagulated venous whole blood. It is intended for in-vitro diagnostic use by healthcare professionals in a laboratory environment to monitor long term glycemic control of persons previously diagnosed with diabetes. This test is not intended for use in the diagnosis of or screening for diabetes or for use on neonates.

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

510(k) Number: k192987

Date of Summary: March 26, 2020

Product Name: Aina HbA1c Monitoring System 2

Sponsor:
Jana Care, Inc.
8 Saint Mary's St., Suite 936
Boston, MA 02215

Correspondent:
MDC Associates, Inc.
Fran White, President
180 Cabot Street
Beverly, MA 01915
Phone: (978) 705 5011
Fax: (866) 540 3448
Email: regulatory@mdcassoc.com

Common Name: Assay, glycosylated hemoglobin

Regulation Number: 864.7470

Classification: LCP, Class II

Substantial Equivalency

Characteristic	**Jana Care, Inc.** **Aina HbA1c Monitoring System 2** (New Device)	**Alere Technologies AS** **Afinion HbA1c, Afinion AS100 Analyzer** K151809 (Predicate Device)
Similarities		
Intended Use	The Aina HbA1c Monitoring System 2 consists of the Aina 2 Automated HbA1c Device, the Aina Device, Aina HbA1c Test Kits, mobile device, and the Aina Mobile Application. It is intended to be used for quantitative measurement of %HbA1c (DCCT/NGSP) and mmol/mol HbA1c (IFCC) in human anticoagulated venous whole blood. It is intended for in-vitro diagnostic use by healthcare professionals in a laboratory environment to monitor long term	Alere Afinion™ HbA1c is an *in vitro* diagnostic test for quantitative determination of glycated hemoglobin (% hemoglobin A1c, % HbA1c) in human whole blood. The measurement of % HbA1c is recommended as a marker of long-term metabolic control in persons with diabetes mellitus.

Characteristic	**Jana Care, Inc.** **Aina HbA1c Monitoring System 2** (New Device)	**Alere Technologies AS** **Afinion HbA1c, Afinion AS100 Analyzer** K151809 (Predicate Device)
	glycemic control of persons previously diagnosed with diabetes. This test is not intended for use in the diagnosis of or screening for diabetes or for use on neonates.	
Indications for Use	Same as Intended Use.	Measurement of %HbA1c in human whole blood as a marker of long term metabolic control in persons with diabetes mellitus.
Assay Method	Boronate affinity	Same
Assay target	Glycosylated hemoglobin (HbA1c)	Same
Measuring Range	4.4-13.4% HbA1c	4-15% HbA1c
Differences		
Sample Type	Anticoagulated venous whole blood in K_2-EDTA	Capillary blood (from finger prick), Anticoagulated venous whole blood in EDTA, heparin, or citrate.
Sample Volume	5 µL	1.5 µL
Test Time	3 minutes	3.5 minutes
Total Hemoglobin Range	7.2-20 g/dL	6-20 g/dL
Testing Temperature	18 to 40°C	18 to 30°C

Intended Use/Indications for Use

The Aina HbA1c Monitoring System 2 consists of the Aina 2 Automated HbA1c Device, the Aina Device, Aina HbA1c Test Kits, mobile device, and the Aina Mobile Application. It is intended to be used for quantitative measurement of %HbA1c (DCCT/NGSP) and mmol/mol HbA1c (IFCC) in human anticoagulated venous whole blood. It is intended for in-vitro diagnostic use by healthcare professionals in a laboratory environment to monitor long term glycemic control of persons previously diagnosed with diabetes. This test is not intended for use in the diagnosis of or screening for diabetes or for use on neonates.

Device Description

The system consists of the Aina 2 Automated HbA1c Device for sample processing that connects to a smartphone via Bluetooth, the Aina Device for optical test strip readout, Aina HbA1c Test Kits which contain all the reagents necessary for running each HbA1c test, and the Aina Mobile Application. The Aina Device is a reflectance-based colorimetric sensor device that connects to the mobile device through the audio jack. The smartphone runs the Aina Mobile Application,

which is software that allows for user interaction and illustrates the step-by-step testing process on its touchscreen. The Aina Mobile Application software is responsible for analyzing the optical signals measured by and transferred to it by the Aina Device, including applying analysis algorithms to compute the HbA1c reading. In addition, the Aina Mobile Application controls the functioning of the Aina 2 Automated HbA1c Device by sending it commands via Bluetooth. Streck A1c-Cellular control solutions can be used for regular quality control checking of the system.

Methodology

The Aina HbA1c Test utilizes the boronate affinity method. The Aina HbA1c Test Kit consists of test strips, reagents, wash buffers, capillary tubes for sample collection, and pipette tips. The reagent contains a lysing agent and a blue boronic acid conjugate. When blood is added to the reagent, the erythrocytes are lysed and all hemoglobin precipitates. The boronic acid conjugates binds to the glycosylated hemoglobin. An aliquot of the reaction mixture is applied to the test strip and all the precipitated hemoglobin, conjugate-bound and unbound, remains on top of the filter. Any unbound boronate is removed with the wash buffer. The precipitate is evaluated by measuring the blue (glycosylated hemoglobin) and the red (total hemoglobin) color intensity respectively with the Aina Device, the ratio between them being proportional to the percentage of the glycosylated hemoglobin in the sample.

Limitations of the Test

- The allowed operating temperature range is 18 to 40°C (64 to 104°F). The recommended range is 20 to 25°C (68 to 77°F)
- The Aina HbA1c Monitoring System 2 is intended to be used at altitudes of up to 2000 meters (6562 feet). The HbA1c readings may be affected at an altitude above 2000 meters (6562 feet).
- The reagent and wash buffer must be stored in the designated temperature range (2 to 8°C). Test results may be inaccurate if they are stored outside of this temperature range for more than 2 hours.
- Do not use the reagent and wash buffer if kept at room temperature for more than 2 hours.
- Use only fresh venous whole blood. Do not use serum or plasma.
- The Aina HbA1c Monitoring System 2 is not intended for point-of-care use.
- This test should not be used in monitoring daily glucose control and should not be used to replace daily home testing of urine and blood glucose levels.
- This test is not intended for use in the diagnosis of or screening for diabetes.
- This test is not intended for use on neonates.
- This test should not be used for analyzing samples from patients with conditions causing shortened red blood cell survival, such as hemolytic diseases, pregnancy and significant acute or chronic blood loss.
- Hemoglobinopathies may interfere with glycated hemoglobin analysis. The results from the Aina HbA1c Monitoring System 2 show that there is no significant interference for samples containing Hemoglobin C (≤ 50%), Hemoglobin D (≤ 43%), Hemoglobin E (≤ 31%), Hemoglobin S (≤ 42%), and Hemoglobin A2 (≤ 6.5%).

- Acetylated, carbamylated, and labile-glycated hemoglobin derivatives generated with normal and diabetic specimens by incubation with acetylsalicylic acid, sodium cyanate, and glucose at concentrations up to 126.1, 32.5, and 1000 mg/dL respectively do not interfere with the assay.
- Samples with a hemoglobin concentration lower than 7.2 g/dL or higher than 20 g/dL can cause inaccurate test results.

WARNING: The Aina HbA1c assay has significant negative interference from Hemoglobin F (HbF). HbA1c results are invalid for patients with abnormal amounts of HbF, including those with known Hereditary Persistence of Fetal Hemoglobin.

Reference Range

	NGSP	IFCC
Target in Diabetes	< 7.0%	< 53 mmol/mol

Reference: American Diabetes Association Standards of Medical Care in Diabetes 2018

Performance Data: Bench Studies

Blood Sample Repeatability

A 20-day repeatability study was conducted to evaluate the performance of the Aina system as per CLSI EP05-A3.

Table 1: Repeatability of the Aina system with blood samples across 3 lots of Aina HbA1c Test Kits

Sample	N	Mean HbA1c %	Repeatability (Within-Run)		Between Run		Between Lot		Between Day		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
Normal	240	5.4	0.2	3.6	0.06	1.2	0.1	2.4	0.1	1.7	0.2	4.2
Elevated	240	6.1	0.2	3.0	0.03	0.5	0.1	1.4	0.1	2.0	0.2	3.7
High	240	11.1	0.3	2.9	0.1	0.9	0.2	2.0	0.1	1.0	0.4	3.2

Control Repeatability

A 20-day repeatability study was conducted to evaluate the performance of the Aina system as per CLSI EP05-A3. The study was performed using two commercial quality controls with target values of <6% and >10% HbA1c.

Table 2: Repeatability of the Aina system with control solutions

Control Level	N	Mean HbA1c %	Repeatability (Within-Run)		Between Run		Between Day		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%
Level 1	80	5.9	0.14	2.4	0.07	1.2	0.15	2.6	0.22	3.7
Level 2	80	13.4	0.26	2.0	0.21	1.5	0.18	1.3	0.38	2.8

Linearity/Assay Reportable Range

A linearity study was conducted in accordance with CLSI EP06-A. Testing was conducted using venous whole blood specimens collected in K_2-EDTA.

A linear regression was calculated based on the theoretical vs measured % HbA1c values:
y(%HbA1c) = 1.01x – 0.08; R=0.998

Based on the results of this study, the Aina system has a linear range from 4.4% to 13.4%.

Interfering Substances

The objective of this study was to assess the known endogenous and exogenous substances that could interfere with the assay. This study was performed as per CLSI EP07-A3. Results demonstrated that no significant interference was observed for the following substances up to the listed concentrations.

Table 3: Potential endogenous interfering substances

Interferent	Concentration
Bilirubin (conjugated)	35 mg/dL
Bilirubin (unconjugated)	66 mg/dL
Triglycerides	2000 mg/dL
Cholesterol	500 mg/dL
Glucose	1500 mg/dL
Rheumatoid Factor	1000 IU/mL
Total Protein	9.3 g/dL
Fructosamine	750 µmol/L

Table 4: Potential exogenous interfering substances

Interferent	Concentration
Acetylsalicylic acid	65 mg/dL
Ascorbic Acid	30 mg/dL
Acetaminophen	30 mg/dL
Glyburide	20 mg/dL
Ibuprofen	50 mg/dL
Metformin	5.1 mg/dL
Rifampicin	6 mg/dL
Salicylic Acid	60 mg/dL

Cross Reactivity with Hemoglobin Derivatives

Results demonstrated that Acetylated Hb up to 126.1 mg/dL acetylsalicylic acid, Carbamylated Hb up to 32.5 mg/dL sodium cyanate, and Labile A1c up to 1000 mg/dL glucose do not interfere with this assay.

Hemoglobin Variants

The objective of this study was to evaluate the interference effect of hemoglobin variants, as found in patients with natural hemoglobinopathies, in the quantitative measurement of HbA1c using the Aina system on venous whole blood samples.

The results from the Aina HbA1c Monitoring System 2 show that there is no significant interference for samples containing Hemoglobin C (≤50%), Hemoglobin D (≤43%), Hemoglobin E (≤31%), Hemoglobin S (≤ 42%), and Hemoglobin A2 (≤ 6.5%).

WARNING: The Aina HbA1c assay has significant negative interference from Hemoglobin F (HbF). HbA1c results are invalid for patients with abnormal amounts of HbF, including those with known Hereditary Persistence of Fetal Hemoglobin.

Specimen Stability

A study was conducted to evaluate the stability of venous whole blood samples when stored at 2 to 8°C. The results show that whole blood samples are stable for use on the system when stored for up to 10 days within 2 to 8°C.

Performance Data: Clinical Studies

To demonstrate accuracy of the system, fresh prospective venous whole blood was collected with K_2-EDTA as an anticoagulant from study participants at three (3) clinical sites and then tested on the Aina HbA1c Monitoring System 2 by trained healthcare professionals in a laboratory environment. Clinical performance of the Aina HbA1c Monitoring System 2 was compared to the Tosoh G8 reference method. Regression analysis (n=132) was performed to compare the results from the Aina HbA1c Monitoring System 2 to the Tosoh G8 using both Passing-Bablok and Weighted Deming analysis.

Table 5: Summary of regression results

Method	Slope	95% CI	y-Intercept	95% CI
Passing-Bablok	1.0	0.9792 - 1.041	-0.20	-0.4929 - 0.0377
Weighted Deming	1.003	0.9679 - 1.038	-0.1924	-0.4465 - 0.0618

Conclusion

The clinical and analytical tests performed for the Jana Care Aina HbA1c Monitoring System 2 demonstrate that the system is safe, effective, and substantially equivalent to the legally marketed predicate device based on intended use, principle and the performance characteristics presented above.