DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 29, 2016

TAIDOC TECHNOLOGY CORPORATION
PAUL LIU
REGULATORY AFFAIRS SPECIALIST
6F, NO. 127, WUGONG 2ND RD. WUGU DISTRICT
NEW TAIPEI CITY, 24888 TAIWAN

Re: K142664
Trade/Device Name: URight Hemoglobin A1c System,
FORA A1c System
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: II
Product Code: LCP, JJE, JJX
Dated: January 21, 2016
Received: January 27, 2016

Dear Paul Liu:

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)*
K142664

Device Name
URight Hemoglobin A1c System

Indications for Use *(Describe)*

The URight Hemoglobin A1c System is intended to quantitatively measure the percent of hemoglobin A1c in capillary finger-stick or venous whole blood collected in EDTA (K2 and K3) or sodium heparin for clinical laboratory and point of care use. The measurement of hemoglobin A1c concentration is for use in monitoring long-term glucose control of persons with diabetes. The system is for in vitro diagnostic use and is not for use in diagnosis or screening of diabetes or for neonatal use.

The URight Hemoglobin A1c Control Solution is intended for use as quality control material for the URight Hemoglobin A1c System.

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)*

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)*
K142664

Device Name
FORA A1c System

Indications for Use *(Describe)*

The FORA A1c System is intended to quantitatively measure the percent of hemoglobin A1c in capillary finger-stick or venous whole blood collected in EDTA (K2 and K3) or sodium heparin for clinical laboratory and point of care use. The measurement of hemoglobin A1c concentration is for use in monitoring long-term glucose control of persons with diabetes. The system is for in vitro diagnostic use and is not for use in diagnosis or screening of diabetes or for neonatal use.

The FORA A1c Control Solution is intended for use as quality control material for the FORA A1c System.

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.

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Section 9 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: K142664

1. Submitter Information

Company Name:	TaiDoc Technology Corporation
Contact Person:	Paul Liu
Title:	Regulatory Affairs Specialist
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E-mail:	paul@taidoc.com.tw
Prepared Date:	January 21st, 2016

2. Device name

Proprietary Name:	URight Hemoglobin A1c System URight Hemoglobin A1c Control Solution FORA A1c System FORA A1c Control Solution
Common Name:	Glycosylated hemoglobin assay Discrete photometric chemistry analyzer Analyte controls
Product Code:	LCP JJE JJX

Classification Panel:	Hematology Clinical Chemistry Clinical Chemistry
Classification:	Class II Class I Class I
Regulation Citation:	21 CFR 864.7470, Hemoglobin A1c test system 21 CFR 862.2160, Discrete photometric chemistry analyzer for clinical use. 21 CFR862.1660, Quality control material (assayed and unassayed)

3. Predicate Device

Proprietary Name:	DCA VANTAGE (k071466) HEMOGLOBIN A1C REAGENT SET (K031539)
Common Name:	Glycosylated hemoglobin assay Analyte controls

4. Intended Use

<u>URight Hemoglobin A1c System</u>

The URight Hemoglobin A1c System is intended to quantitatively measure the percent of hemoglobin A1c in capillary finger-stick or venous whole blood collected in EDTA (K2 and K3) or sodium heparin for clinical laboratory and point of care use. The measurement of hemoglobin A1c concentration is for use in monitoring long-term glucose control of persons with diabetes. The system is for in vitro diagnostic use and is not for use in diagnosis or screening of diabetes or for neonatal use.

The URight Hemoglobin A1c Control Solution is intended for use as quality control material for the URight Hemoglobin A1c System.

FORA A1c System

The FORA A1c System is intended to quantitatively measure the percent of hemoglobin A1c in capillary finger-stick or venous whole blood collected in EDTA (K2 and K3) or sodium heparin for clinical laboratory and point of care use. The measurement of hemoglobin A1c concentration is for use in monitoring long-term glucose control of persons with diabetes. The system is for in vitro diagnostic use and is not for use in diagnosis or screening of diabetes or for neonatal use.

The FORA A1c Control Solution is intended for use as quality control material for the FORA A1c System.

5. Device Description:

The hemoglobin A1c system is comprised of a fully automated desktop electric spectrophotometer that measures HbA1c in capillary or venous whole blood samples collected in EDTA (K2 and K3) or sodium heparin using a dedicated cartridge, which is pre-filled with the reagent; latex (reagent 1), antibody and sample dilute solution (reagent 2). The hemoglobin A1c system shines a light through the test material and measures the quantity of hemoglobin A1c in the total hemoglobin (HbA1c %) based on the lot-specific reagent parameters and changes in light absorbency caused by antigen-antibody reactions.

Two levels of hemoglobin A1c control are provided for routine quality checks - level 1 in the normal HbA1c range and level 2 in the elevated HbA1c range. The HbA1c controls are lyophilized hemolysates prepared from packed human erythrocytes.

6. Test Principle:

The hemoglobin A1c system is an immuno-turbidimetric method enhanced by latex particles using a two-reagent sequence. Hemolysate is mixed with the reagent 1. Addition of the reagent 2 leads to agglutination complexes, formed by the interaction between latex-bound HbA1c and the corresponding antibodies. Turbidity created by these aggregates is proportional to the amount of latex-bound HbA1c therefore is proportional to the % of HbA1c in the total hemoglobin.

7. Comparison with Predicate

Hemoglobin A1c test system

Similarities and Differences		
Item	New Device	Predicate Device
Intended Use	Quantitative measurement of the percent Hemoglobin A1c in human whole blood.	Same
Methodology	Immuno-turbidimetric	Same
Sample Type	whole blood samples, venous whole blood (K2 or K3 EDTA or sodium heparin) or capillary whole blood from fingertips	Whole blood and finger stick samples
Recommended Testing Environment	Professional and Point of Care Use	Same
Analytical Range	4.0-16.0%	2.5 – 14.0%
Reagent storage	2-8℃	Same

Hemoglobin A1c control

Similarities and Differences		
Item	New Device	Predicate Device
Intended Use	Intended for use as quality control materials	Same
Format (Material)	Lyophilized hemolysates	Same
Levels	Level 1, Level 2	Same
Storage Conditions	2-8℃	Same
Use Lifetime	3 weeks after reconstitution	4 weeks after reconstitution

8. Performance Characteristics:

• Linearity

Varying amounts two fresh EDTA blood samples, 4.3% and 13% HbA1c, were mixed to in different proportions to obtain 11 samples. Two additional samples, 14.3% and 15.5% HbA1c, were created by spiking fresh blood sample. A linear regression was calculated

based on the Tosoh G8 vs. measured % HbA1c values.

Slope	Intercept	R2	Recovery (%)
1.0037	0.0355	0.9913	95-104

• **Precision**

Two levels HbA1c control solutions and three levels of blood samples were used for precision evaluation on three different sites. The expected values were determined by Tosoh G8. Within-run precision was perform measurements from each sample with 20 tests. Between-run and Between day precision were tested from each sample in duplicate twice a day for 20 days.

Sample	**Site**	**n**	**Expected value**	**Within run**			**Between run**			**n**	**Between day**		
				Mean	**SD**	**%CV**	**Mean**	**SD**	**%CV**		**Mean**	**SD**	**%CV**
Control solution Low level	1	20	5.7	5.9	0.22	3.75%	5.8	0.10	1.79%	80	5.8	0.20	3.48%
	2	20		5.7	0.24	4.24%	5.7	0.13	2.19%	80	5.7	0.20	3.47%
	3	20		5.8	0.25	4.32%	5.7	0.11	1.99%	80	5.7	0.22	3.82%
	Combined	60		5.8	0.25	4.35%	5.7	0.12	2.02%	240	5.7	0.21	3.61%
Control solution High level	1	20	11.3	11.4	0.44	3.88%	11.3	0.24	2.11%	80	11.3	0.43	3.78%
	2	20		11.4	0.44	3.85%	11.2	0.25	2.22%	80	11.2	0.44	3.89%
	3	20		11.2	0.40	3.55%	11.3	0.25	2.24%	80	11.2	0.46	4.12%
	Combined	60		11.3	0.43	3.77%	11.3	0.24	2.16%	240	11.2	0.44	3.92%
Blood sample Low level	1	20	5.5	5.3	0.15	2.87%	5.3	0.10	1.88%	80	5.3	0.20	3.79%
	2	20		5.3	0.22	4.14%	5.3	0.11	2.01%	80	5.3	0.21	4.04%
	3	20		5.3	0.17	3.18%	5.3	0.13	2.54%	80	5.3	0.20	3.70%
	Combined	60		5.3	0.18	3.46%	5.3	0.12	2.18%	240	5.3	0.20	3.87%
Blood sample Middle level	1	20	7.7	7.9	0.33	4.18%	7.8	0.13	1.62%	80	7.8	0.30	3.91%
	2	20		7.7	0.38	4.95%	7.7	0.10	1.36%	80	7.6	0.29	3.85%
	3	20		7.6	0.27	3.58%	7.7	0.16	2.08%	80	7.7	0.30	3.90%
	Combined	60		7.7	0.35	4.50%	7.7	0.14	1.79%	240	7.7	0.30	3.92%
Blood sample High level	1	20	10.3	10.4	0.34	3.26%	10.4	0.17	1.66%	80	10.4	0.36	3.43%
	2	20		10.4	0.37	3.60%	10.5	0.18	1.67%	80	10.5	0.36	3.39%
	3	20		10.4	0.35	3.43%	10.5	0.17	1.63%	80	10.5	0.37	3.49%
	Combined	60		10.4	0.35	3.38%	10.5	0.18	1.70%	240	10.5	0.36	3.46%

• **Accuracy**

A method comparison study was performed with 149 EDTA venous blood and 146 capillary blood patient samples in three different sites. Samples were analyzed on TD-4601 Hemoglobin A1c Reagent Cartridge and compared with Tosoh G8 analyzer.

Site No.	Sample type	No. of tests	regression line	R^2
1	Capillary	49	y = 1.002x - 0.016	0.9834
1	K_2EDTA venous blood	49	y = 1.018x - 0.101	0.9807
2	Capillary	48	y = 1.015x - 0.044	0.9846
2	K_2EDTA venous blood	50	y = 1.022x - 0.076	0.9885
3	Capillary	49	y = 0.958x + 0.280	0.9849
3	K_3EDTA venous blood	50	y = 0.968x + 0.160	0.9861

• **Interference**

The following interfering substances at the indicated concentrations produce less than 6% deviation when tested at indicated concentration: Acetaminophen 20 mg/dL, Glibenclamide 0.19 mg/dL, Ibuprofen 50 mg/dL, Metformin 4 mg/dL, Triglycerides 3000 mg/dL, Bilirubin (unconjugate) 20 mg/dL, Ascorbic acid 3 mg/dL, Rheumatoid factor 26 IU/mL, Carbamylated Hb 5 mmol/L, and Acetylated Hb 5 mmol/L. The testing results also indicate there is no significant interference for HbC ≤37.4%, HbD ≤48.5%, HbE ≤21.4% and HbA2 ≤7.0%. HbF shows interference at 21.2% and HbS shows interference at 20.3%. HbF and HbS levels tested with this assay show interference and samples containing HbF or HbS will show a lower than expected HbA1c result.

• **Matrix comparison**

The study was performed using 135 samples, with a HbA1c range from 4.5-13%, collected from 3 POC sites in the matrix of capillary blood, K2EDTA venous blood, K3EDTA venous blood and sodium heparin venous blood.

Matrix comparison	Regression line	R^2
EDTA vs. Capillary	y = 0.978x + 0.301	0.9896
Sodium heparin vs. Capillary	y = 0.982x + 0.227	0.9885
Sodium heparin vs. EDTA	y = 0.0.999x - 0.033	0.9879

9. Limitations

- This test is not for screening or diagnosis of diabetes or neonatal use

- For clinical laboratory and point-of care use
- For prescription use only
- This test should not be used in monitoring daily glucose control
- This test should not be used to replace daily home testing of urine and blood glucose levels
- 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
- HbF and HbS levels tested with this assay show interference and samples containing HbF or HbS will show a lower than expected HbA1c result

10. Reference range

The American Diabetes Association (ADA) expected value range is 4.0-6.0% HbA1c for people without diabetes. The American Diabetes Association's (ADA) most recent Clinical Practice Recommendation for diabetes specified a treatment goal of less than 7% and suggests additional action when HbA1c level is above 8%.

HA1c Value	Glycemic Goal
<8% HbA1c	Less stringent
<7% HbA1c	General (Non-Pregnant Adult)
<6.5% HbA1c	More stringent

As recommended by the ADA, patients in the range of 5.7-6.4% HbA1c would be in the category of increased risk for diabetes.

Source: American Diabetes Association. Diabetes Care 38 (2015): Suppl. 1. S8-S40

11. Conclusion

Based on the information provided in this submission, the **URight Hemoglobin A1c System / FORA A1c System and URight Hemoglobin A1c Control Solution / FORA A1c Control Solution** are substantially equivalent to the predicate device.