May 4, 2018

TaiDoc Technology Corporation
Anne Kuo
Regulatory Affairs Specialist
B1-7F, No. 127, Wugong 2nd Rd., Wugu District
New Taipei City, 24888
Taiwan

Re: K173345
Trade/Device Name: TD-4140 Smart Dongle Blood Glucose plus B-ketone Monitoring System
Regulation Number: 21 CFR 862.1435
Regulation Name: Ketones (nonquantitative) test system
Regulatory Class: Class I, meets the limitation of exemptions 21 CFR 862.9(c)(5)
Product Code: JIN
Dated: March 31, 2018
Received: April 4, 2018

Dear Anne Kuo:

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 Part 801 and Part 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for 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)*
K173345

Device Name
TD-4140 Smart Dongle Blood Glucose plus β-ketone Monitoring System

Indications for Use *(Describe)*
The TD-4140 Smart Dongle Blood Glucose plus β-ketone Monitoring System consists of the Smart Dongle meter, Smart Dongle blood glucose test strips, Smart Dongle β-ketone test strips, and the Procheck mobile application as the display component of the system. This system is intended to be used for the quantitative measurement of glucose (sugar) and β-ketone in fresh capillary whole blood from the finger.

This 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. It is intended to be used by a single person and should not be shared. This system should not be used for the diagnosis of or screening for diabetes, nor 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.

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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: **K173345**

1. Applicant Information

Company	TaiDoc Technology Corporation
Contact Person	Anne Kuo
Title	Regulatory Affairs Specialist
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2. Device name

Proprietary Name	TD-4140 Smart Dongle Blood Glucose plus β-ketone Monitoring System
Common Name	β-Ketone monitoring system
Product Code	JIN, Nitroprusside, Ketones (Urinary, Non-Quant.)
Classification	Clinical chemistry
Panel	JIN: Class I
Classification	21 CFR §862.1435 Ketones (nonquantitative) test system
Regulation Citation	Meets limitations of exemptions 21 CFR 862.9(c)(5)

3. Predicate Device

k161738	FORA ADVANCED GD40 Blood Glucose and β-Ketone Monitoring System

4. Intended Use

The **TD-4140 Smart Dongle Blood Glucose plus β-ketone Monitoring System** consists of the Smart Dongle meter, Smart Dongle blood glucose test strips, Smart Dongle β-ketone test strips, and the Procheck mobile application as the display component of the system. This system is intended to be used for the quantitative measurement of glucose (sugar) and β-ketone in fresh capillary whole blood from the finger.

This 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. It is intended to be used by a single person and should not be shared. This system should not be used for the diagnosis of or screening for diabetes, nor for use on neonates.

5. Device Description

The **TD-4140 Smart Dongle Blood Glucose plus β-ketone Monitoring System** consists of the Smart Dongle meter, Smart Dongle blood glucose test strips, Smart Dongle β-ketone test strips, and the Procheck mobile application as the display component of the system.

This system is compatible to iPhone series, including iPhone 4/4s, 5/5s, 6/6 plus, 6s/6s plus, and iPod touch 5. These products have been designed, tested, and proven to work together as a system to produce accurate test results. The Smart Dongle meter should only be used with the Smart Dongle Blood Glucose test strips and the Smart Dongle β-ketone test strips.

6. Comparison to the Predicate

Item	**Predicate device**	**Proposed device**
510(k) no.	**k161738**	**-**
Proprietary name	FORA ADVANCED GD40 Blood Glucose and β-Ketone Monitoring System	TD-4140 Smart Dongle Blood Glucose plus β-ketone Monitoring System
Intended use	Quantitative measurement of glucose and β-ketone in fresh capillary whole blood from the finger by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. For single person use and should not	Quantitative measurement of glucose and β-ketone in fresh capillary whole blood from the finger by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. For single person use and should not

Item	Predicate device	Proposed device
510(k) no.	**k161738**	**-**
	be shared. Not be used for the diagnosis of or screening for diabetes, nor for use on neonates.	be shared. Not be used for the diagnosis of or screening for diabetes, nor for use on neonates.
Glucose		
Glucose assay method	Glucose dehydrogenase	Same as predicate
Glucose measuring range	20 ~ 600 mg/dL	Same as predicate
Sample type	Capillary finger stick	Same as predicate
Sample size	0.9 uL	1.0 uL
Hematocrit range	20% ~ 70%	Same as predicate
Analysis time	5 seconds	Same as predicate
Coding	Code Card	No coding
Ketone		
Assay method	β-hydroxybutyrate dehydrogenase	Same as predicate
Measuring range	0.1 ~ 8.0 mmol/L	Same as predicate
Sample type	Capillary finger stick	Same as predicate
Ketone sample size	1.0 uL	Same as predicate
Hematocrit range	20% ~ 70%	Same as predicate
Analysis time	10 seconds	Same as predicate
Coding	Code card	Same as predicate
Operating conditions	10 ℃ – 40 ℃, 10% – 90% R.H.	10 ℃ – 40 ℃, 10% – 85% R.H.
Power source	AAA x 2	Powered by mobile platform
Display	LCD	Displayed on mobile platform: iPhone 4, iPhone 4s, iPhone 5, iPhone 5s, iPhone 6, iPhone 6 plus, iPhone 6s, iPhone 6s plus and iPod touch 5th generation
Data storage	1000 sets	1 set (latest result) All data stored in the mobile device
Data transmission	RS-232 4 Poles	Headphone jack

7. Test Principle

Glucose measurement is based on electrochemical biosensor technology using the enzyme Glucose Dehydrogenase to catalyze the formation of gluconolactone from the oxidation of glucose whereby two electrons are produced. The electrical current resulting from this enzymatic reaction is measured and correlated to glucose concentration by the meter. The magnitude of the current is proportional to the

concentration of glucose in the sample. The test strip is calibrated to display the equivalent of plasma glucose values to allow comparison of results with laboratory methods.

Using the same technology, β-hydroxybutyrate (β-ketone) is converted by β-hydroxybutyrate dehydrogenase and the magnitude of electrical current resulting from this enzymatic reaction is proportional to the amount of β-hydroxybutyrate present in the sample.

The measurement result is transmitted to a compatible mobile device via headphone jack. The App within this system is used for analysis and storage of the data for personal healthcare.

8. Performance Characteristics

Clinical and non-clinical studies were conducted to test, verify and validate with respect to the predicate device to establish the performance of this system. The data demonstrates that this system is substantially equivalent to the predicate device.

Accuracy – blood glucose

Results for glucose concentration < 75 mg/dL	Within 5 mg/dL	Within 10 mg/dL	Within 15 mg/dL
	57 (73.1%)	78 (100%)	78 (100%)

Results for glucose concentration ≥ 75 mg/dL	Within 5%	Within 10 %	Within 15 %	Within 20 %
	272 (67.7%)	386 (96.0%)	402 (100%)	402 (100%)

Precision – blood glucose

Intermediate precision

Control solutions	Level 1	Level 2	Level 3
Mean (mg/dL)	49.6	139.4	335.4
SD (mg/dL)	2.17	4.37	10.10
CV (%)	4.38%	3.13%	3.01%

Repeatability

Blood samples	Level 1	Level 2	Level 3	Level 4	Level 5
Mean (mg/dL)	49.7	91.2	128.3	227.8	390.2
SD (mg/dL)	2.18	2.95	4.06	7.18	12.06
CV (%)	4.39%	3.23%	3.16%	3.15%	3.09%

Accuracy – β-ketone

		Test results of the test device fulfilling specified error limits (Capillary blood sampling subjects N=120)				
At ketone value < 2 mmol/L	n	Within ±0.3 mmol/L		Within ±0.5 mmol/L		
	89	84 (94.4%)		89 (100%)		
At ketone value ≥ 2 mmol/L	n	Within 5%	Within 10%	Within 15%	Within 20%	Within 25%
	31	14 (45.2%)	26 (83.9%)	29 (93.5%)	31 (100%)	31 (100%)

Precision – β-ketone

Repeatability precision: The test was performed with venous blood sample that contained three different levels of β-ketone.

Ketone Level	Overall Mean (mmol/L)	SD (mmol/L)	CV (%)
Level 1	0.520	0.055	10.59
Level 2	2.887	0.090	3.12
Level 3	5.030	0.153	3.05

Intermediate precision: The test was performed with two levels of β-ketone control solution.

Control solutions	Overall Mean (mmol/L)	SD (mmol/L)	CV (%)
Level 1	0.593	0.037	6.15
Level 2	2.583	0.070	2.71

The β-ketone test strip shows acceptable precision and no variation among lots.

Linearity/assay reportable range

The linearity of a blood β-Ketone system is the degree to which its results (y-axis) form a straight line when plotted against the defined concentrations of samples (x-axis). The reportable range of a system may be established by demonstrating the linearity of its results with samples of known β-Ketone concentration. The system was validated when β-Ketone concentrations are (<0.1 mmol/L) and (>8.0mmol/L) displaying "Lo" and "Hi" symbol respectively. The system shows a high linearity over a blood β-Ketone range of 0.1 to 8.0 mmol/L.

Analytical specificity

Seventy-eight potential interfering substances consisting of exogenous substances (substances originating from outside the body such as therapeutic agents or vitamins) of the most commonly used critical care drugs and endogenous substances (substances produced or originating from with the body) were chosen.

- The following table lists the concentrations of substances at which **no** significant interference is observed.

Substance	Highest concentration tested at which **no** significant interference is observed (mg/dL)	Substance	Highest concentration tested at which **no** significant interference is observed (mg/dL)
Acetylsalicylic Acid	50	Lactitol	1000
Acetoacetate	20	Lidocaine	6
Acetone	70	Magnesium	5 mM
Acyclovir	3.1	Maltitol	1000
Allopurinol	5	Maltose	1000
Amitriptylline	0.27	Mannitol	1000
Amoxicillin	12.5	Metaproterenol	1.81
Ampicillin	5	Metformin HCl	50
Aspirin (Salicylic Acid)	60	Metoprolol	0.3
Atenolol	10	Naproxen	100
Bicarbonate	336 (40 mM)	Nifedipine	0.17
Bile Acids	6	Nortriptyline	0.15

(Cholic Acid)			
Caffeine	10	Penicillin	12
Calcium	5 mM	Phenytoin	10
Chloride	140 mM	Piroxicam	5
Clonidine	2	Potassium	10 mM
Creatinine	5	Sodium	200 mM
Digoxin	0.16	Sorbitol	1000
Diphenhydramine	1	Sulfamethoxazole	120
Enalapril	0.15	Sulfate	5 mM
Erythromycin	20	Terfenadine	0.45
Ephedrine Hcl	60	Tetracycline	4
Erythromycin	20	Theophylline	25
Estrone	0.1	Tolbutamide	64
Famotidine	0.13	Total Protein (gamma-Globulin)	12000
Fluoxetine	0.8	Urea	600
Fructose	1000	Vancomycin	25
Furosemide	2	Verapamil	0.45
Glyburide	1.07	Vitamin E	20
Ibuprofen	55	Warfarin	2
Isomalt	1000	Xylitol	1000
Lactose	1000	Xylose	1000

- The following table lists the concentrations of substances at which interference was greater than ±10%.

Substance	Lowest Concentration above which interference >10% is observed (mg/dL)	Substance	Lowest Concentration above which interference >10% is observed (mg/dL)
Captopril	>500	Unconjugated bilirubin	>20
Ascorbic acid	> 4	Cholesterol	>500
Dopamine	> 0.09	Triglycerides (Lipemic Sample)	>1500
Levo – Dopa	> 0.6	Galactose	>13.87 mmol/L
Gentisic Acid	>1.8	Methyl-DOPA	>59.18
Paracetamol	>25	Tolazamide	> 321
Uric acid	>24	N-Acetylcysteine	>0.038

9. Conclusion

Based on the information provided in this submission, the TD-4140 Smart Dongle Blood Glucose plus β-ketone Monitoring System is substantially equivalent to the predicate device, FORA ADVANCED GD40 Blood Glucose and β-Ketone Monitoring System (k161738).