June 16, 2022

TaiDoc Technology Corporation
Jacky Chou
Director of Regulatory Affairs
B1-7F, No. 127, Wugong 2nd Rd., Wugu District
New Taipei City, 24888
Taiwan

Re: K201037
Trade/Device Name: FORA ADVANCED GD40 Glucose, β-Ketone and Cholesterol Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, JIN, CHH
Dated: February 24, 2022
Received: March 1, 2022

Dear Jacky Chou:

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.
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)*
k201037

Device Name
FORA ADVANCED GD40 Glucose, β-Ketone and Cholesterol Monitoring System

Indications for Use *(Describe)*
The FORA ADVANCED GD40 Glucose, β-Ketone and Cholesterol Monitoring System consists of the FORA ADVANCED GD40 meter, the FORA ADVANCED GD40 Blood Glucose strips, the FORA ADVANCED GD40 β-Ketone strips, and the FORA ADVANCED GD40 Total Cholesterol strips.

The FORA ADVANCED GD40 Glucose, β-Ketone and Cholesterol Monitoring System is intended for the quantitative measurement of glucose, beta-hydroxybutyrate (β-ketone), and cholesterol in fresh capillary whole blood from the finger. This system is intended for single-patient home use and should not be shared. This device is intended for use by patients with diabetes. It is only for use outside the body (in vitro diagnostic use).

Glucose and β-ketone measurements are used as an aid to monitor the effectiveness of a diabetes control program. Glucose measurements should not be used for the diagnosis of or screening for diabetes.

Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Cholesterol should be measured at the frequency recommended by your healthcare provider.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submission Number: k201037

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

A. Submitter Information

Company Name:	TaiDoc Technology Corporation
Contact Person:	Jacky Chou
Title:	Director of Regulatory Affairs
Address:	B1-7F, No. 127, Wugong 2nd Rd., Wugu District, New Taipei City, 24888, Taiwan
Phone:	+886-2-6625-8188
Fax:	+886-2-6625-0288
E-mail:	jacky.chou@taidoc.com.tw
Prepared Date:	June 16th, 2022

B. Regulatory information:

Proprietary Name:	FORA ADVANCED GD40 Glucose, β-Ketone and Cholesterol Monitoring System
Product Code:	NBW - Blood Glucose Test System, Over-the-Counter JIN - nitroprusside, ketones (urinary, non-quant.) CHH - enzymatic esterase--oxidase, cholesterol
Classification Panel:	75, Clinical chemistry
Classification:	Class II (glucose test) Class I, meets the limitations of exemption 21 CFR 862.9(c)(5) (β-ketone test) Class I, meets the limitations of exemption 21 CFR 862.9(c)(4) (cholesterol test)

Regulation Citation:	21 CFR 862.1345, Glucose test system 21 CFR 862.1435 Ketones (nonquantitative) test system 21 CFR 862.1175 Cholesterol (total) test system.

C. Predicate Devices

FORA ADVANCED GD40 and FORA ADVANCED GD40 pro Blood Glucose and ß-Ketone Monitoring Systems (K161738)

Mission Cholesterol Monitoring System, Mission Cholesterol Pro Monitoring System (K163406)

D. Indications for Use

The FORA ADVANCED GD40 Glucose, β-Ketone and Cholesterol Monitoring System consists of the FORA ADVANCED GD40 meter, the FORA ADVANCED GD40 Blood Glucose strips, the FORA ADVANCED GD40 β-Ketone strips, and the FORA ADVANCED GD40 Total Cholesterol strips.

The FORA ADVANCED GD40 Glucose, β-Ketone and Cholesterol Monitoring System is intended for the quantitative measurement of glucose, beta-hydroxybutyrate (β-ketone), and cholesterol in fresh capillary whole blood from the finger. This system is intended for single-patient home use and should not be shared. This device is intended for use by patients with diabetes. It is only for use outside the body (in vitro diagnostic use).

Glucose and β-ketone measurements are used as an aid to monitor the effectiveness of a diabetes control program. Glucose measurements should not be used for the diagnosis of or screening for diabetes.

Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Cholesterol should be measured at the frequency recommended by your healthcare provider.

E. Device Description:

FORA ADVANCED GD40 Glucose, β-Ketone and Cholesterol Monitoring System includes the FORA ADVANCED GD40 Meter, analyte-specific test strips (FORA ADVANCED GD40 Blood Glucose Test Strips, FORA ADVANCED GD40 Blood Cholesterol Test Strips, and FORA ADVANCED GD40 Blood Ketone Test Strips) and control solutions (FORA Glucose Control Solutions, β-Ketone Control Solutions and Total Cholesterol Control Solutions).

The glucose/β-ketone test strips and control solutions utilized in the FORA ADVANCED GD40 Glucose, β-Ketone and Cholesterol Monitoring System are the same as the predicate, FORA ADVANCED GD40 Blood Glucose and β-Ketone Monitoring System (k161738).

F. 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; Cholesterol esters in serum are completely hydrolyzed by cholesterol esterase to free cholesterol and free fatty acids, whereby liberated cholesterol, plus any endogenous free cholesterol, are oxidized by cholesterol oxidase and the magnitude of electrical current resulting from this enzymatic reaction is proportional to the amount of cholesterol present in the sample.

G. Summary of Technological Characteristics and Comparison to the Predicate

The similarities and differences between the predicate and proposed device are summarized in Table 1 and Table 2.

Table 1: Similarities and differences between the predicate and proposed device (Glucose and Ketone)

Similarities and Differences: System (Test and Instrument) for blood Glucose and Ketone		
Feature or Characteristic	**Predicate: FORA ADVANCED GD40 Blood Glucose and β-Ketone Monitoring System (k161738)**	**Candidate: FORA ADVANCED GD40 Glucose, β-Ketone and Cholesterol Monitoring System**
Intended Use	It is intended for the quantitative measurement of glucose in fresh capillary whole blood from the finger, and for the quantitative measurement of β-ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the finger. The FORA ADVANCED GD40 is intended for in vitro diagnostic use and is intended for single-patient use as an aid to monitor the effectiveness of a diabetes control program. The system should not be used for the diagnosis of or screening for diabetes.	Same
Setting to be used	Over-the-counter Home use	Same
Test Range	20 – 600 mg/dL	Same
Sample Type	Fingertip Capillary whole blood	Same
Sample Volume	0.9 μl	Same
Test Time	5 sec	Same
Calibration	Automatic	Same
Operating Principle	Enzymatic	Same
Data storage	1000 Results with Date/Time	Same
Weight	71 g	Same
Analytes	Glucose and β-Ketone	Glucose, β-Ketone, and Cholesterol

Table 2: Similarities and differences between the predicate and proposed device (Cholesterol)

Similarities and Differences: System (Test and Instrument) for blood Cholesterol		
Feature or Characteristic	**Predicate: Mission Cholesterol Monitoring System (k163406)**	**Candidate: FORA ADVANCED GD40 Glucose, β-Ketone and Cholesterol Monitoring System**
Intended Use	It is intended to be used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Cholesterol should be measured at the frequency recommended by the healthcare provider.	Same
Setting to be used	Over-the-counter Home use and Prescription use	Over-the-counter Home use
Test Range	100 – 400 mg/dL	Same
Sample Type	Fingertip Capillary whole blood	Same
Sample Volume	10 μl	5 μl
Test Time	< 2 min	60 sec
Calibration	Calibration strip	Same
Operating Principle	Enzymatic	Same
Data storage	200 Results with Date/Time	1000 Results with Date/Time
Weight	145 g	71 g

H. Summary of Testing:

Non-clinical and clinical studies were conducted to test, verify and validate the performance of the proposed device. Results from these studies show that all performance criteria were met.

Non-Clinical Testing Summary: Design verification and validation testing was performed to ensure that the FORA ADVANCED GD40 Glucose, β-Ketone and Cholesterol Monitoring System met design specifications and requirements. Testing activities included electrical/mechanical safety tests, functional performance tests (precision, linearity, interference, flex studies) as well as disinfection, cleaning, and robustness studies. Software validation was performed for this moderate level of concern device per FDA Guidance Content of Premarket Submissions for Software Contained in Medical Devices.

Clinical Testing Summary: A user evaluation confirmed the system accuracy, operation according to design, and ease of use to support the intended use as described in the proposed labeling.

I. Conclusion:

The results of software validation and performance verification testing confirmed that the FORA ADVANCED GD40 Glucose, β-Ketone and Cholesterol Monitoring System is substantially equivalent to that of the predicate devices.