DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 10, 2016

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

Re: K161738
Trade/Device Name: FORA ADVANCED GD40 Blood Glucose and ß-Ketone Monitoring System
FORA ADVANCED GH40 pro Blood Glucose and ß-Ketone Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR, JIN, JJX
Dated: September 26, 2016
Received: October 3, 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,

Katherine Serrano -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)*

Device Name

FORA ADVANCED GD40 Blood Glucose and β-Ketone Monitoring System

Indications for Use *(Describe)*

FORA ADVANCED GD40 Blood Glucose and β-Ketone Monitoring System 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, nor for use on neonates.

FORA ADVANCED GD40 Blood Glucose Test Strips are for use with the FORA ADVANCED GD40 Blood Glucose and β-Ketone Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the finger. The FORA ADVANCED GD40 Blood β-Ketone Test Strips are for use with the FORA ADVANCED GD40 Blood Glucose and β-Ketone Meter to quantitatively measure β-ketone in fresh capillary whole blood samples drawn from the finger.

β-Ketone Control Solutions are intended for use with FORA ADVANCED GD40 Blood Glucose and β-Ketone Monitoring System to check that the meters 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)

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)*

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."

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)*

Device Name

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

Indications for Use *(Describe)*

FORA ADVANCED GD40 pro Blood Glucose and β-Ketone Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the finger, and from venous, and neonatal capillary heelstick whole blood, and for the quantitative measurement of β-ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the finger, and from venous whole blood. The FORA ADVANCED GD40 pro is intended for in vitro diagnostic use and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with single-use, auto-disabling lancing devices. The system should not be used for the diagnosis of or screening for diabetes.

FORA ADVANCED GD40 pro Blood Glucose Test Strips are for use with the FORA ADVANCED GD40 pro Blood Glucose and β-Ketone Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, and from venous and neonatal whole blood. The FORA ADVANCED GD40 pro Blood β-Ketone Test Strips are for use with the FORA ADVANCED GD40 pro Blood Glucose and β-Ketone Meter to quantitatively measure β-ketone in fresh capillary whole blood samples drawn from the fingertips and from venous whole blood.

β-Ketone Control Solutions are intended for use with FORA ADVANCED GD40 Blood Glucose and β-Ketone Monitoring System to check that the meters and test strips are working together properly and that the test is performing correctly.

Type of Use *(Select one or both, as applicable)*

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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:_____

1. Submitter Information

Company Name:	TaiDoc Technology Corporation
Contact Person:	Paul Liu
Title:	Regulatory Affairs Specialist
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Fax:	+886-2-6625-0288
E-mail:	paul@taidoc.com.tw
Prepared Date:	June 19th, 2016

2. Regulatory information:

Proprietary Name:	FORA ADVANCED GD40 Blood Glucose and β-Ketone Monitoring System FORA ADVANCED GD40 pro Blood Glucose and β-Ketone Monitoring System β-Ketone Control Solution
Common Name:	Blood Glucose and β-Ketone Monitoring System
Product Code:	NBW - Blood Glucose Test System, Over-the-Counter LFR - Glucose Dehydrogenase JIN - nitroprusside, ketones (urinary, non-quant.) JJX - single (specified) analyte controls (assayed and unassayed)
Classification Panel:	75, Clinical chemistry
Classification:	Class II (glucose) Class I (β-Ketone)
Regulation Citation:	21 CFR §862.1345, Glucose test system

21 CFR 862.1435 Ketones (nonquantitative) test system
21 CFR 862.1660 Quality control material (assayed and unassayed)

3. Predicate Device

Nova Max Plus Blood Glucose and β-Ketone Monitor System (k091547)

4. Intended Use

Single-patient use

FORA ADVANCED GD40 Blood Glucose and β-Ketone Monitoring System 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, nor for use on neonates.

FORA ADVANCED GD40 Blood Glucose Test Strips are for use with the FORA ADVANCED GD40 Blood Glucose and β-Ketone Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the finger. The FORA ADVANCED GD40 Blood β-Ketone Test Strips are for use with the FORA ADVANCED GD40 Blood Glucose and β-Ketone Meter to quantitatively measure β-ketone in fresh capillary whole blood samples drawn from the finger.

β-Ketone Control Solutions are intended for use with FORA ADVANCED GD40 Blood Glucose and β-Ketone Monitoring System to check that the meters and test strips are working together properly and that the test is performing correctly.

Multiple-patient use

FORA ADVANCED GD40 pro Blood Glucose and β-Ketone Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the finger, and from venous, and neonatal capillary heelstick whole blood, and for the quantitative measurement of β-ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the finger, and from venous whole blood. The FORA ADVANCED GD40 pro is intended for in vitro diagnostic use and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with single-use, auto-disabling lancing devices. The system should not be used for the diagnosis of or screening for diabetes.

FORA ADVANCED GD40 pro Blood Glucose Test Strips are for use with the FORA ADVANCED GD40 pro Blood Glucose and β-Ketone Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, and from venous and neonatal whole blood. The FORA ADVANCED GD40 pro Blood β-Ketone Test Strips are for use with the FORA ADVANCED GD40 pro Blood Glucose and β-Ketone Meter to quantitatively measure β-ketone in fresh capillary whole blood samples drawn from the fingertips and from venous whole blood.

β-Ketone Control Solutions are intended for use with FORA ADVANCED GD40 Pro Blood Glucose and β-Ketone Monitoring System to check that the meters and test strips are working together properly and that the test is performing correctly.

5. Device Description:

The FORA ADVANCED GD40/GD40 Pro Blood Glucose and β-Ketone Monitoring System consists of: FORA ADVANCED GD40/GD40 Pro Blood Glucose and β-Ketone Meter (same as meter cleared under k101509, with addition of ketone testing capability), FORA ADVANCED GD40/GD40 Pro Glucose Test Strips, FORA Glucose Control Solutions (cleared under K093724), FORA ADVANCED GD40/GD40 Pro β-Ketone Test Strips, and β-Ketone Control Solutions.

6. Comparison to the Predicate:

The FORA ADVANCED GD40/GD40 Pro Blood Glucose and β-Ketone Monitoring System uses the same fundamental technology and has same intended use as the predicate device Nova Max Plus Blood Glucose and β-Ketone Monitor System (k091547).

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 β-ketone control solution contain known amount of β-hydroxybutyrate that reacts with β-ketone test strip intended for use as quality checks.

8. Performance Studies:

The performance of the FORA ADVANCED GD40/GD40 Pro Blood Glucose and β-Ketone Monitoring System was studied in the laboratory and clinical settings by healthcare professionals and lay users. The studies demonstrate that the intended users can obtained blood Glucose and β-Ketone results that are substantially equivalent to the current methods for blood glucose and β-Ketone measurement.

9. Conclusion:

Based on the results of laboratory and clinical studies provided in this submission, FORA ADVANCED GD40/GD40 Pro Blood Glucose and β-Ketone Monitoring System is substantially equivalent to the predicate devices.