August 9, 2018

ForaCare Inc.
Anne Kuo
Regulatory Affairs Specialist
893 Patriot Dr., Suite D
Moorpark, CA 93021

Re: K173505
Trade/Device Name: FORA GTel Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: July 9, 2018
Received: July 10, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K173505

Device Name
FORA GTel Blood Glucose Monitoring System

Indications for Use *(Describe)*
The FORA GTel Blood Glucose Monitoring System consists of the FORA GTel Blood Glucose Test Strip and the FORA GTel Blood Glucose meter.
The FORA GTel Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. It is intended for in vitro diagnostic use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. It is intended to be used by a single person and should not be shared.

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
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*"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

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 **K173505**.

## 1. Applicant Information

| | |
|---|---|
| Company | ForaCare Inc. |
| Address | 893 Patriot Dr., Suite D, Moorpark, CA 93021 USA |
| Phone | 1-805-498-8188 |
| Fax | 1-805-498-7188 |
| Contact Person | Anne Kuo |
| Title | Regulatory Affairs Senior Specialist |
| Phone | +886-2-6625-8188 #1195 |
| Fax | +886-2-6625-0608 |
| E-mail | ra.cert@taidoc.com.tw<br>anne.kuo@taidoc.com.tw |

## 2. Proposed Device Information

| | | |
|---|---|---|
| Proprietary Name | FORA GTel Blood Glucose Monitoring System | |
| Regulation Description | Glucose test system | |
| Review Panel | Clinical Chemistry | |
| Product Code | NBW | Blood Glucose Test System, Over-the-Counter |
| Regulation Number | 21 CFR §862.1345 | |
| Device Class | 2 | |

## 3. Predicate Device Information

| | |
|---|---|
| Proprietary Name | FORA GD43 Blood Glucose Monitoring System |
| Regulation Description | Glucose test system |
| Manufacturer | TaiDoc Technology Corporation |
| 510(k) number | K143467 |

## 4. Intended Use:

The FORA GTel Blood Glucose Monitoring System consists of the FORA GTel Blood Glucose Test Strip and the FORA GTel Blood Glucose meter.

The FORA GTel Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. It is intended for in vitro diagnostic use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. It is intended to be used by a single person and should not be shared.

## 5. Device Description:

The FORA GTel Blood Glucose Monitoring System consists of FORA GTel blood glucose meter and FORA GTel blood glucose test strip which have been designed, tested, and proven to produce accurate blood glucose test result only when used in combination.

## 6. Test Principle:

The system measures the amount of sugar (glucose) in whole blood. The glucose testing is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter measures the current, calculates the blood glucose level, and displays the result. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

## 7. Summary of Technological Characteristics and Comparison to the Predicate

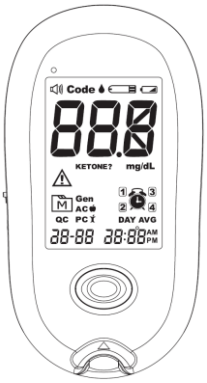
The FORA GTel Blood Glucose Monitoring System is substantially equivalent to the predicate device, both in terms of intended use and technological characteristics.

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

*Table 1: Similarities between the Predicate and Proposed Devices*

| Characteristic | Predicate Device | Proposed Device |
|---|---|---|
| Detection method | Amperometric glucose biosensor | Same |
| Enzyme | Glucose dehydrogenase (GDH) | Same |
| Electrode material | Gold | Same |
| Blood volume | 0.5 µl | Same |
| Reaction time | 5 seconds | Same |
| Measurement range | 20~600 mg/dL | Same |
| Code type | Code Card | Same |
| Sample type | Capillary whole blood | Same |
| Ketone warning | no | Same |
| Glucose warning | No Hi/Lo Indicator | Same |
| Measurement mode | Gen/AC/PC/QC | Same |
| Day average | 7-, 14-, 21-, 28-, 60- and 90-day | Same |
| Power saving | Idling for 180 seconds | Same |
| Alarm clock | 4 | Same |
| Memory capacity | 1000 measurements | Same |
| Strip ejector | Yes | Same |
| Operating condition | 46.4˚F~113˚F (8˚C~45˚C) | Same |
| Meter storage condition | -4˚F~140˚F (-20˚C~60˚C) | Same |
| Strip storage condition | 35.6˚F~86.0˚F (2˚C~30˚C) | Same |

*Table 2: Differences between the Predicate and Proposed Devices*

| Characteristic | Predicate Device | Proposed Device |
|---|---|---|
| Appearance |  |  |
| Dimension (mm) | 110 (L) x 57 (W) x 25 (H) | 98 (L) x 55 (W) x 15.5 (H) |
| Weight | 71 (without battery) | 63.2 (without battery) |
| Intended use | • for use in the quantitative measurement of glucose in fresh capillary whole blood from the fingertip and alternative sites (palm, forearm and upper arm)<br>• for in vitro diagnostic use by people with diabetes at home<br>• for single person and should not be shared<br>• not for the diagnosis of or screening for diabetes<br>• not for neonates | • for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger<br>• for in vitro diagnostic use by people with diabetes mellitus at home<br>• for single person and should not be shared<br>• not for the diagnosis of or screening for diabetes<br>• not for neonates |
| Hematocrit range | 20%~70% | 20%~60% |
| Accuracy | ± 15 mg/dL if ≤ 75 mg/dL;<br>± 20 % if > 75 mg/dL | 95% within ± 15%;<br>99% within ± 20% |
| AST | Yes, Palm, forearm and upper arm | No |
| Measurement Unit | Fix mg/dL | Either mg/dL or mmol/L<br>(Default mg/dL) |
| Talking function | No | Yes |
| LCD type | LCD | TFT LCD |
| Power source | 2 x 1.5V AAA batteries | 1 x 3.7V Li-Ion<br>rechargeable battery |
| Data transmission | RS-232 4 Poles | 3G |

## 8. Summary of Testing

Non-clinical and clinical studies were conducted to test, verify and validate the performance of the proposed device according to FDA Guidance issued on October 11, 2016: *Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use.* 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 GTel Blood Glucose 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, robustness, and shelf life 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.

## 9. Traceability

This system is compared to the YSI-2300 Glucose Analyzer in the clinical and non-clinical studies. The YSI is calibrated with NIST (SRM) 917A reference material.

## 10. Conclusion:

Based on the information provided in this submission, the FORA GTel Blood Glucose Monitoring System is believed to be substantially equivalent with the predicate device.