DEC 1 5 2011

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: K112275

1. Submitter's Identification:
   TaiDoc Technology Corporation
   3F, 5F, No.127, Wugong 2nd Rd., Wugu District, New Taipei City, 248, Taiwan

   Correspondent:
   Teling Hsu
   Regulatory Affairs Specialist
   Tel: +886-2-6625-8188 #1176
   Fax: +886-2-6625-0288
   Email: teling.hsu@taidoc.com.tw

   Prepared date: Aug 03, 2011

2. Device name:
   Proprietary name: FORA Premium V10 Blood Glucose Monitoring System

   Regulatory information:
   A. Regulation section: 21 CFR 862.1345 Glucose Test System
   B. Classification: Class II
   C. Product Code: CGA, Glucose Oxidase, Glucose
      NBW, System, Test, Blood Glucose, Over The Counter
   D. Panel: Clinical Chemistry (75)

3. Intended Use:

   The FORA Premium V10 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: palm, forearm, upper-arm, calf and thigh. It is intended for use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. This system is intended to be used by a single person and should not be shared. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

   The alternative site testing in the FORA Premium V10 Blood Glucose Monitoring System can be used only during steady-state blood glucose conditions.

   The FORA Premium V10 Test Strips are for use with the FORA Premium V10 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper-arm, calf and thigh.

   This meter has some speaking functions but is not intended for use by the visually impaired.

4. Device Description:

   The system consists of three main products: the meter, test strips, and control solutions. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use only FORA test strips and FORA control solutions (cleared under k093724) with the FORA Premium V10 Blood Glucose Monitoring System.

5. Substantial Equivalence Information:

   A. Predicate device name: FORA V30 blood glucose monitoring system
   B. Predicate K number: K093635
   C. Comparison with predicate:

   The modified FORA Premium V10 Blood Glucose Monitoring System has the following similarities to the predicate device:

   - same operating principle,
   - same fundamental scientific technology,
   - incorporate the same basic circuit design,
   - incorporate the same materials,
   - same shelf life

- packaged using the same materials, and
- manufactured by the same process.

The modifications encompass:

- Modification in the physical appearance
- Minor software modifications of the glucose meter
- Change of the data transmission method from RS-232 to USB
- Labeling change due to the above modifications

6. Test Principle:
   The detection and measurement of glucose in blood is by an electrochemical biosensor technology using glucose oxidase.

7. Performance Characteristics:
   FORA Premium V10 Blood Glucose Monitoring System has the same performance characteristics as the predicate device.

   A comparison of system accuracy performance demonstrated that the FORA Premium V10 Blood Glucose Monitoring System and the FORA V30 Blood Glucose Monitoring System are substantially equivalent.

   Software verification and validation testing confirmed that the performance, safety and effectiveness of the FORA Premium V10 Blood Glucose Monitoring System are equivalent to the predicate device.

8. Conclusion:
   Based on the information provided in this submission, the FORA Premium V10 Blood Glucose Monitoring System is substantially equivalent to the predicate FORA V30 blood glucose monitoring system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

TAIDOC TECHNOLOGY CORPORATION
C/O TELING HSU
3F-5F NO. 127 WUGONG 2ND RD.
WUGU DISTRICT
NEW TAIPEI CITY
CHINA (TAIWAN) 24888

DEC 15 2011

Re: k112275
Trade Name: FORA Premium V10 Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA
Dated: November 16, 2011
Received: November 22, 2011

Dear Ms. Hsu:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/Medical Devices/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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k112275

Device Name: FORA Premium V10 Blood Glucose Monitoring System, model TD-4124

Indications for Use:

The FORA Premium V10 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: palm, forearm, upper-arm, calf and thigh. It is intended for use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. This system is intended to be used by a single person and should not be shared. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

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Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K112275

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