JUL - 6 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: k092688

1. Submitter Information

Company name	TaiDoc Technology Corporation
Contact person	Teling Hsu
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Date Prepared	July 4th, 2011

2. Name of Device

Proprietary Names	FORA POCT S10 Blood Glucose Monitoring System
Common Name	Blood Glucose Test System
Classification Name	Class II devices (21 CFR Section 862.1345)
Product Code	LFR

3. Predicate Device

Trade/Proprietary Name:	TaiDoc Professional I Glucose Test Strips
Common/Usual Name:	Blood Glucose Test System
Manufacturer	TaiDoc Technology Corporation
510 (k) Number	K082169

4. Device Description

The FORA POCT S10 Blood Glucose Monitoring System is designed to quantitatively measure the concentration of glucose in capillary and venous whole blood. The test principle of the system utilize an electrochemical method-based meter and dry reagent biosensor (test strips) for blood glucose testing. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative

measurement of glucose in whole blood and control solutions.

5. Intended Use

The FORA POCT S10 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose with fresh capillary whole blood from the finger and venous whole blood samples. It is indicated for multiple patients use by health care professionals in health care facilities as an aid in monitoring the effectiveness of diabetes control program. The system is only used with single-use lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus. It is not intended for use on neonates.

The FORA POCT S10 Blood Glucose test strips are for the quantitative measurement of glucose with fresh capillary whole blood from the finger and venous whole blood samples. The FORA POCT S10 test strips are for use only with the FORA POCT S10 Blood Glucose meter.

6. Comparison to Predicate Device

The proposed FORA POCT S10 Blood Glucose Meter is in conjunction with TaiDoc Pro I Glucose Test Strips which is cleared as the predicate device and work with the proposed device as a functional system.

This system use amperometry for blood glucose measurement. The test is based on the measurement of electrical current generated by the reaction of glucose with reagents of the strip.

7. Performance Studies

The performance of FORA POCT S10 Blood Glucose Monitoring System has the same performance characteristics as the predicate device.

The studies of software verification and validation testing, system accuracy, and meter reliability test demonstrated that the performance of this system meets its intended use.

8. Conclusion

FORA POCT S10 Blood Glucose Monitoring System demonstrates satisfactory performance and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

JUL 0 6 2011

TaiDoc Technology Corporation
c/o Ms. Teling Hsu
Regulatory Affairs Specialist
3F, 5F, No. 127, Wugong 2nd Road, Wugu Township
Taipei County, Taiwan 24888

Re: k092688
Trade/Device Name: FORA POCT S10 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862. 1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: LFR
Dated: June 28, 2011
Received: June 30, 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 class II (Special Controls), 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 Parts 801 and 809), 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 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number: k092688

Device Name: FORA POCT S10 Blood Glucose Monitoring System

Indications for Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

Division Sign-off
Office of In Vitro Diagnostic Devices
Evaluation and Safety
510(k) K092688