

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

k111029

B. Purpose for Submission:

New 510(k) for diabetes data management software accessory for use with compatible glucose meters such as the FORA POCT S10 Blood Glucose Monitoring System (K092688)

C. Measurand:

Whole blood glucose

D. Type of Test:

Diabetes data management system

E. Applicant:

TaiDoc Technology Corporation

F. Proprietary and Established Names:

FORA POCT Management System

G. Regulatory Information:

1. Regulation section:

21CFR Sec.- 862.1345-Glucose test system.

21CFR Sec.-862.2100 - Calculator/data processing module for clinical use.

2. Classification:

Class II and I respectively

3. Product code:

NBW - System, Test, Blood Glucose, Over the Counter

JQP-Calculator/Data Processing Module, for Clinical Use

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indication(s) for use below

2. Indication(s) for use:

The FORA POCT Management System is a data management software and designed for using in hospital or health institute environment. Patient historical data transmitted is able to be reviewed and analyzed in this system.

The FORA POCT Management System may not be used as a substitute for direct medical intervention or emergency care. Interpretation of the information

collected and transmitted requires clinical judgment by an appropriate healthcare professional.

3. Special conditions for use statement(s):
Prescription use
4. Special instrument requirements:
FORA POCT S10 Blood Glucose Monitoring System

I. Device Description:

The role of FORA POCT Management System is data management software that runs on a common Intranet secure server platform. The system assists healthcare professionals to store, review, analyze and evaluate the historical data. Those data are transmitted from the device’s memory to the system via cable connections.

The FORA POCT Management System is designed for use in hospital or health care facility. This system provides comprehensive database management including test results of blood glucose measurements and quality controls, stock management of test strips and control solutions, meter configurations, information of patients, operators and facility administrators along with statistical graphs, charts and other helpful tools.

J. Substantial Equivalence Information:

1. Predicate device name(s):
AtLast® Data Management Software (DMS)
2. Predicate 510(k) number(s):
K010605
3. Comparison with predicate:

Item	Proposed device	Predicate (k010605)
Brand name	FORA POCT Management System	AtLast® Data Management Software (DMS)
Submitter	TaiDoc Technology Corporation	Amira Medical

Intended Use	<p>The FORA POCT Management System is data management software. Patient historical data transmitted is able to be reviewed and analyzed in this system.</p> <p>The FORA POCT Management System may not be used as a substitute for direct medical intervention. Interpretation of the information collected and transmitted requires clinical judgment by an appropriate healthcare professional.</p>	Same
Intended users	Clinical users	Same
Site of use	Clinical settings	Same
Data collection software	Proprietary software	Same
Communication method with management system	Via broadband intranet connection	Same
Communication method with Meter	A USB cable is used for meter to connect to PC, and software.	A custom interface cable is used for meter to connect to PC, and software.
Types of Test Data which is applied	Glucose levels	Same
Communications protocol	Proprietary	Same
Data Presentation	By Reports, Graphs and Charts	Same

K. Standard/Guidance Document Referenced (if applicable):

None were referenced

L. Test Principle:

FORA POCT Management System is an accessory to compatible meters, which use specific test principles, such as the FORA POCT S10 Blood Glucose Monitoring System (k092688)

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
Presented in k092688
 - b. *Linearity/assay reportable range:*
Presented in k092688
 - c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Presented in k092688
 - d. *Detection limit:*
Presented in k092688
 - e. *Analytical specificity:*
Presented in k092688
 - f. *Assay cut-off:*
Presented in k092688
2. Comparison studies:
 - a. *Method comparison with predicate device:*
Presented in k092688
 - b. *Matrix comparison:*
Not Applicable
3. Clinical studies:
 - a. *Clinical Sensitivity:*
Not Applicable
 - b. *Clinical specificity:*
Not Applicable
 - c. Other clinical supportive data (when a. and b. are not applicable):
Not Applicable
4. Clinical cut-off:
Not Applicable
5. Expected values/Reference range:
Presented in k092688

N. Instrument Name:

FORA POCT Management System

O. System Descriptions:

1. Modes of Operation:
Microsoft Internet Explorer 6.0, 7.0, 8.0 or later versions (with ActiveX installation allowed)

- *Personal computer with 2.0 GHz or higher processor clock speed recommended
- *Higher than 512MB of RAM recommended
- *Monitor with at least 800x600 pixels resolution
- *Intranet accessibility with at least 1Mbps bandwidth

*USB 2.0 port and USB cable

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?:

Yes or No

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?:

Yes or No

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes or No

3. Specimen Identification:

Glucose test results are identified from registered meters according to different items such as operator ID (bar-coded), patient ID (bar-coded), meter ID, strip ID, and test date/time.

4. Specimen Sampling and Handling:

Not Applicable

5. Calibration:

Not Applicable

6. Quality Control:

The system contains a Quality Control program that allows the administrator to query, review and comment on QC data from the registered meters, according to different items, such as operators, meters, strips and control solution. In addition to the comment codes which operators may note from meters, the system displays the distribution graphs plotted with means and bounds and allows adding review comments for administrative functions.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:

The sponsor provided test results for the validation of the interoperability of the FORA POCT Management System and FORA POCT S10 Blood Glucose meter for: functionality system test, and mass data and multiple devices upload, plus interoperability with Laboratory Information Systems (LIS).

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.