

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

A. 510(k) Number:

k091814

B. Purpose for Submission:

Modifications to a previously cleared device that include: the addition of speaking functions, change in the type of coding function, an increase in memory, a name change, and a change in size and weight of meter.

C. Measurand:

Capillary whole blood glucose and blood pressure

D. Type of Test:

Quantitative, electrochemical biosensor, glucose oxidase
Non-invasive Oscillometric

E. Applicant:

Taidoc Technology Corporation

F. Proprietary and Established Names:

FORA D20 Blood Glucose Plus Blood Pressure Monitoring System
TD-3263 Blood Glucose Plus Blood Pressure Monitoring System

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1345; Glucose test system
21 CFR 870.1130; Noninvasive blood pressure measurement system

2. Classification:

Class II, Class I (reserved)

3. Product code:

NBW, System, Test, Blood Glucose, Over The Counter.
CGA, Glucose Oxidase, Glucose
DXN, System, Measurement, Blood-Pressure, Non-Invasive

4. Panel:

Clinical Chemistry (75)
Cardiovascular (74)

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indications(s) for use:

The FORA D20/TD-3263 Blood Glucose plus Blood Pressure 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: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and 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, or for testing on neonates.

The alternative site testing in this system can be used only during steady-state blood glucose conditions.

The system is also intended to be used to measure non-invasively the systolic and diastolic blood pressure and pulse rate of an adult individual at home. The blood pressure is measured by using a technique in which an inflatable cuff is wrapped around the arm. The cuff circumference is limited to 9.4” – 13.8”.

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

3. Special conditions for use statement(s):

- For in vitro diagnostic use only
- Over-the-Counter and Prescription Use

The following limitations apply to the glucose measurement function:

- Not intended for use on neonates
- Not for the diagnosis of or screening for diabetes mellitus
- Not to be used for patients who are dehydrated, hypotensive, in shock, and individuals in hyperglycemic-hyperosmolar state, with or without ketosis.

- Critically ill patients should not be tested with a blood glucose meter.
- Allows testing on the fingertip, palm, forearm, upper arm, calf, or thigh
- Alternate site testing can only be used during steady-state blood glucose conditions
- Not intended for use by the visually impaired

The following limitations apply to the blood pressure measurement function:

- Allows testing only on the arm
- Not for use in the presence of common arrhythmia

4. Special instrument requirements:

FORA D20/TD-3263 Blood Glucose meter

I. Device Description:

The FORA D20 Blood Glucose Plus Blood Pressure Monitoring System and the TD-3263 Blood Glucose Plus Blood Pressure Monitoring System are two names for the same meter (same model number).

These systems consist of: a glucose meter, lancing device, arm cuff, and Owner's manual. Test strips, lancets, and two levels of control solutions, Normal and High (cleared in k041107) are not included with the meter and are available separately.

The changes to the memory function and the addition of voice features affect both the glucose measuring component and the blood pressure measuring component. The modifications to the coding function only affect the blood glucose measuring component.

The device has an internal established code, where the user must select the proper code number (code numbers 21-25) from the monitor that matches the one on the test strip vial.

The system contains some voice features, but is not intended for use by the visually impaired.

J. Substantial Equivalence Information:

1. Predicate device name(s):

TaiDoc Technology Corporation; Clever Chek TD-3250 Blood Glucose plus Blood Pressure Monitoring System

2. Predicate 510(k) number(s):

k062800

3. Comparison with predicate:

Blood glucose measurement function

Similarities		
Item	New Device	Predicate (k062800)
Indications for use	<p>The FORA D20/TD-3263 Blood Glucose plus Blood Pressure 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: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and 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, or for testing on neonates.</p> <p>The alternative site testing in this system can be used only during steady-state blood glucose conditions.</p> <p>The system is also intended to be used to measure non-invasively the systolic and diastolic blood pressure and pulse rate of an adult individual at home. The blood pressure is measured by using a technique in which an inflatable cuff is wrapped around the arm. The cuff circumference is limited to 9.4” – 13.8”.</p>	Same
Test Principle	Amperometry, measuring a current produced by a chemical for the measurement of blood glucose.	Same
Sample Type	Fresh capillary whole blood	Same
Sample Site	Fingertip, the palm, the forearm, the upper-arm, the calf and the thigh	Same
Sample volume	0.7 µL	Same
Measuring time	7 sec	Same
Measurement range	20-600 mg/dL	Same

Blood pressure measurement function

Similarities		
Item	Device	Predicate (k062800)
Test Principle	Oscillometric method	Same
Measurement Range	Blood pressure: 0 to 300 mmHg Pulse Rate: 40 to 199 beats/min	Same

Differences		
Item	Device	Predicate (k062800)
Memory feature	450 measurement results with date and time	352 measurements with day and time
Speaking functions	Yes	No
Coding function	Select code number from the meter	Insert code strip into the meter
Dimensions (mm)	155x110x69 mm	137x90x54 mm
Weight (g)	340 g without cuff and batteries	250 g without cuff and batteries

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

- ISO15197:2003 - *In vitro* diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
- ISO 14971:2000 – Medical devices – Application of risk management to medical devices.
- CLSI EP-9A: Method Comparison and bias estimation using patient samples; Approved Guideline.
- CLSI EP5-A: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition.

L. Test Principle:

The modifications to the device in this submission are: the addition of speaking functions, change to the type of coding function, an increase in memory, a name change, and a change in size and weight of the meter.

Refer to k062800 for a description of the glucose and blood pressure measuring technologies in this device.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Established in the original submission (k062800)

b. *Linearity/assay reportable range:*

Established in the original submission (k062800)

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The control solutions, Normal and High, with target values of 125 and 300 mg/dL, were originally cleared in k041107.

d. Detection limit:

Established in the original submission (k062800)

e. Analytical specificity:

Established in the original submission (k062800)

f. Assay cut-off:

Established in the original submission (k062800)

2. Comparison studies:

a. Method comparison with predicate device:

Established in the original submission (k062800)

b. Matrix comparison:

Established in the original submission (k062800)

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):

The sponsor provided a readability study and obtained Flesch-Kincaid Grade Level Scores of 7.9 to 8.0 for the User's Manual and Test Strip insert.

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range:

Established in the original submission (k062800)

N. Instrument Name:

FORA D20 Blood Glucose Plus Blood Pressure Monitoring System or TD-3263
Blood Glucose Plus Blood Pressure Monitoring System

O. System Description:

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for additional readings.

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

Yes X (reviewed under k070941) or No _____.

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

Yes _____ or No X .

2. Software:

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

Yes X or No _____.

The applicant has provided documentation that indicates the device was designed and developed under good software life-cycle processes.

3. Specimen Identification:

There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected, and blood pressure is measured directly.

4. Specimen Sampling and Handling:

This device is intended to be used with capillary whole blood from the finger, the palm, the forearm, the upper-arm, the calf and the thigh. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

The meter uses an internal established code. When the test strip is inserted the user must select the correct code number from the meter (code numbers 21 to 25) that matches the number on the test strip vial.

6. Quality Control:

Two levels of control solution (previously cleared in k041107), Normal and High, are available for purchase separately, as stated in the labeling. The users are instructed to test the control solutions when using the meter for the first time, when a new vial of test strips is used, when the user suspects the meter or test strips are not working properly, when the blood glucose results are not consistent with how the user feels, when the test strips are exposed to extreme environmental conditions, or if the meter is dropped.

When a test strip is inserted into the meter the control mode can be activated by pressing “M”. “CTL” will appear on the display. While “CTL” is displayed the results will not be stored in the results memory. An acceptable range for each control level is printed on the test strip vial label. The user is referred to the user manual and customer support for problems and more information.

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

The new device is a modification of the predicate device. The modifications include the addition of speaking functions, change in the type of coding function, an increase in memory, a name change, and a change in size and weight of meter. The following documentation of these modifications as related to software changes was reviewed and found to be acceptable: level of concern, software description, device hazard analysis, software requirements specifications, software design specification, software development environment description, and verification and validation testing.

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.