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

A. 510(k) Number:
k073137

B. Purpose for Submission:
Modification of a cleared device (addition of voice capabilities)

C. Measurand:
Whole blood glucose

D. Type of Test:
Whole Blood Glucose Concentration through a Quantitative Amperometric Assay (Glucose Oxidase)

E. Applicant:
Apex Biotechnology Corp.

F. Proprietary and Established Names:
GlucoSure Voice Blood Glucose Monitoring System

G. Regulatory Information:
1. Regulation section:
   21 CFR § 862.1345, Glucose Test System
   21 CFR § 862.1660, Single (specified) analyte controls (assayed and unassayed)
2. Classification:
   Class II
   Class I (reserved)
3. Product code:
   NBW, CGA, JJX
4. Panel:
   75 (Clinical Chemistry)

H. Intended Use:
1. Intended use(s):
   See indications for use below.
2. Indication(s) for use:
   The GlucoSure Voice Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Testing is done outside the body (In Vitro diagnostic use). The meter includes voice functionality to assist visually impaired users. It is indicated for both lay use by people with diabetes and in a clinical setting by healthcare professionals, as an aid to monitoring levels in Diabetes Mellitus.

The purpose of the control solution test is to validate the performance of the Blood Glucose Monitoring system using a testing solution with a known range of glucose. A control test that falls within the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly.

3. Special conditions for use statement(s):
   - Not for neonatal use
   - Not for screening or diagnosis of diabetes mellitus
   - Alternative site testing is for use at times of steady state only
   - For Over-the-Counter use
   - Not for use in critically ill patients or those in hyperosmolar state

4. Special instrument requirements:
   GlucoSure Voice Blood Glucose Monitoring System

I. Device Description:
The GlucoSure Voice Blood Glucose Monitoring System is based on an electrochemical biosensor technology (electrochemical) and the principle of capillary action. Capillary action at the end of the test strip draws the blood into the action chamber and the blood glucose result is displayed in 6 seconds. The control solutions available are used to test the performance of the device.

J. Substantial Equivalence Information:
1. Predicate device name(s):
   Apex Biotechnology Corp. GlucoTrack Blood Glucose Monitoring System
2. Predicate 510(k) number(s):
   k062799
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase	Glucose Oxidase
Test Range	20 – 600 mg/dL	20 – 600 mg/dL
Volume Required	1 μL	1 μL
Hematocrit Range	30-55%	30-55%
Test Time	6 seconds	6 seconds

Differences		
Item	Device	Predicate
Alternate Site Testing	Yes	No
Voice Output	Yes	No

K. Standard/Guidance Document Referenced (if applicable):
CLSI EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices
CLSI EP6-P: Evaluation of the Linearity of Quantitative Measurement Procedures

ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

L. Test Principle:

Glucose measurement is based on electrical potential caused by the reaction of glucose with the reagents contained on the strip's electrodes. The glucose in the sample is oxidized by the enzyme glucose oxidase, and the current resulting from this enzymatic reaction is measured and converted to glucose concentration by the meter. The magnitude of the current is proportional to the concentration of glucose in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. *Precision/Reproducibility:*
       The sponsor evaluated the within run precision of the device using 20 replicate measurements of 5 concentrations of glucose-adjusted venous whole blood and 2 concentrations of control solutions with 3 strip lots.

       The sponsor also evaluated the between run precision of the device using replicate measurements of venous whole blood samples and glucose controls. Twenty replicates at 5 different concentrations and 2 levels of controls were each tested with 3 strip lots over 20 days. Results met the sponsor's acceptance criteria of a standard deviation ≤ 4.5 mg/dL when the glucose concentration was <75 mg/dL and less than a 6% CV for glucose concentrations ≥ 75 mg/dL. Results are summarized in the table below.

Whole blood samples							
		Within-Run		Between Run		Overall	
Strip lot	Mean (mg/dL)	SD	%CV	SD	%CV	SD	%CV
FS 002i	31	1.73	--	1.24	--	2.46	--
	82	3.18	3.7%	2.01	2.5%	3.57	4.3%
	156	5.82	3.6%	3.90	2.5%	5.82	3.7%
	386	6.46	1.7%	8.70	2.3%	13.34	3.5%
	575	26.55	4.7%	14.36	2.5%	21.15	3.7%
FS 002J	35	2.91	--	1.40	--	3.03	--
	84	2.26	2.8%	2.52	3.0%	3.76	4.5%
	154	6.02	3.9%	4.21	2.7%	6.04	3.9%
	384	13.45	3.5%	5.61	1.5%	12.09	3.1%
	586	21.29	3.6%	8.34	1.4%	16.87	2.9%
FS 002K	34	2.47	--	1.71	--	3.10	--
	83	1.90	2.2%	2.62	3.2%	3.48	4.2%
	158	5.25	3.2%	2.90	1.8%	5.43	3.4%
	380	5.12	1.4%	6.67	1.8%	10.61	2.8%
	576	9.23	1.6%	8.85	1.5%	14.93	2.6%

Control Solution							
		Within-Run		Between Run		Overall	
Strip Lo	Mean (mg/dL)	SD	%CV	SD	%CV	SD	%CV
FS 002i	87	3.97	4.6%	2.05	2.3%	3.94	4.5%
	192	6.38	3.4%	3.85	2.0%	6.92	3.6%
FS 002J	87	3.53	4.0%	2.38	2.7%	4.11	4.7%
	196	7.59	4.0%	3.66	1.9%	6.60	3.4%
FS 002K	90	3.71	4.1%	2.82	3.1%	4.30	4.8%
	194	7.00	3.6%	4.83	2.5%	7.22	3.7%

b. *Linearity/assay reportable range:*
To establish the linearity of the GlucoSure Voice Meter system through the range of 20 to 600 mg/dL glucose adjusted whole blood samples were compared to YSI 2300. The sponsor tested 8 samples that spanned the claimed measuring range 4 times using 10 different meters and 3 different strip lots. Linear regression yields the following statistics:

	Slope	y-intercept	r^2
Strip Lot 1	1.055	-7.128	0.998
Strip Lot 2	1.033	-4.587	0.999
Strip Lot 3	1.049	-7.152	0.998

The sponsor claims 20 mg/dL as the lowest detectable limit in the labeling.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
The controls were evaluated in the predicate device (k062799). The evaluation of the controls in that submission is described below.

The device is traceable to a laboratory analyzer which is calibrated to a glucose standard (NIST SRM 965a).

Stability characteristics of both levels of control solutions were determined using real time aging studies to determine the open vial storage stability at room temperature to be 18 months and unopened vial stability to be 24 months.

The expected values for the two glucose control solutions were established by repeat testing (10 times) on two meters using one lot of strips for both glucose levels. The expected results may change with each new lot, but the control range is listed in the product insert.

d. *Detection limit:*
The measuring range of the GlucoSure Voice Blood Glucose Monitoring System is 20 - 600 mg/dL. This range was verified by the linearity study (above).

e. *Analytical specificity:*
Analytical specificity was evaluated in the predicate device (k062799).

f. *Assay cut-off:*
Not Applicable

2. Comparison studies:
   a. *Method comparison with predicate device:*
   A consumer study was performed with 152 lay-users and a technician (with 6 samples contrived to produce low sample values) to see if glucose readings from the fingertip were comparable to a laboratory glucose reference method and that alternate site testing were comparable to fingertip. The labeling provided to the users was in English only. Each participant performed their own fingerstick and tested their blood using the instructions in the user's manual. The 6 contrived samples ranged from 34.3 - 47.6 mg/dL and the real samples ranged from 48.8 – 478 mg/dL. Results are summarized below using a single finger stick values (where the labeling uses a mean fingerstick value of two results):

Patient	Fingerstick vs. YSI	Palm vs. Patient FingerStick	Forearm vs. Patient FingerStick
Samples < 75 mg/dL within ±15 mg/dL YSI	10/11 (91%)	11/11 (100%)	10/11 (91%)
Samples ≥ 75 mg/dL within ± 20% YSI	141/141 (100%)	141/141 (100%)	139/141 (99%)
Total	151/152 (99%)	152/152 (100%)	149/152 (98%)

Technician	Fingerstick and contrived vs. YSI	Palm vs. Technician FingerStick	Forearm vs. Technician FingerStick
Samples < 75 mg/dL within ±15 mg/dL YSI	17/17 (100%)	11/11 (100%)	11/11 (100%)
Samples ≥ 75 mg/dL within ± 20% YSI	141/141 (100%)	139/141 (99%)	141/141 (100%)
Total	158/158 (100%)	150/152 (99%)	152/152 (100%)

The above studies were performed by lay users that were both normally sited and visually impaired (having severe presbyopia, retinopathy, cataracts, or glaucoma) who used the voice feature.

The sponsor showed the performance of the device by only the visually impaired users by evaluating those users blood glucose and comparing them to YSI as well as a user study to determine if the voice feature was satisfactory to users. The concentration of the samples ranged from 48.8 to 478 mg/dL. The results are summarized below.

Visually Impaired	Fingerstick vs. YSI	Palm vs. Patient FingerStick	Forearm vs. Patient FingerStick
Samples < 75 mg/dL within ±15 mg/dL YSI	2/3 (66%)	3/3 (100%)	3/3 (100%)
Samples ≥ 75 mg/dL within ± 20% YSI	42/42 (100%)	42/42 (100%)	42/42 (100%)
Total	44/45 (98%)	45/45 (100%)	45/45 (100%)

    b. Matrix comparison:
       Not applicable. Capillary whole blood is the only indicated matrix.

3. <u>Clinical studies</u>:
    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 that indicated that the user manual, test strip labeling, and control solution labeling is at an 8th grade reading level or below.

4. <u>Clinical cut-off</u>**:**
    Not Applicable.

5. <u>Expected values/Reference range:</u>
    The sponsor included the following Expected Values for normal glucose levels in their strip labeling:

    74~106 mg/dL before meals[1]
    Less than 140 mg/dL two hours after meal[2]

    1. Stedman,Thomas Lathrop. Stedman's Medical Dictionary, 27th Edition, 1999, pg. 2082.
    2. American Diabetes Association, "Clinical Practice Recommendations 2003." Diabetes Care, Vol 26, Supplement 1, pg. S22.

N. Instrument Name:
    GlucoSure Voice Blood Glucose Monitoring System

O. System Descriptions:
  1. <u>Modes of Operation</u>:
    Each test strip is single use and must be replaced with a new strip for additional readings.
  2. <u>Software</u>:
    FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:
    Yes ___X____ or No _____
  3. <u>Specimen Identification</u>:
    There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.
  4. <u>Specimen Sampling and Handling</u>:
    This device is intended to be used with capillary whole blood from the finger, palm, or forearm only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.
  5. <u>Calibration</u>:

A code number is provided with each batch of test strips to calibrate the meter for that batch. The code number is associated with the meter by a coding card that is inserted into the meter that comes with each vial of test strips. No further calibrations are required of the user.

6. <u>Quality Control</u>:
The sponsor is providing a single level glucose control solution with this device as a "starter kit." There is a "simple kit" in which controls are not provided. Two levels are available for purchase as stated in the labeling. When a test strip is inserted into the meter, a control can be run. An acceptable range for each control level is printed on the test strip vial label. The user is referred to a troubleshooting section of the owner's manual to identify possible reasons control results fall outside these ranges.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:
None

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.