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

I Background Information:

A 510(k) Number

K202534

B Applicant

Apex Biotechnology Corp.

C Proprietary and Established Names

MTM301 Blood Glucose and Ketone Monitoring System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NBW	Class II	21 CFR 862.1345 - Glucose Test System	CH - Clinical Chemistry
JIN	Class I, meets the limitation of exemption 21 CFR 862.9(c)(5)	21 CFR 862.1435 - Ketones (nonquantitative) test system	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Addition of glucose measurement functionality to a previously cleared ketone monitoring system (k182593).

B Measurand:

Glucose and β-hydroxybutyrate in capillary whole blood

C Type of Test:

Quantitative amperometry for glucose and β-hydroxybutyrate

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

MTM301 Blood Glucose and Ketone Monitoring System: MTM301 Blood Glucose and Ketone Monitoring System is comprised of the MTM301 Blood Glucose and Ketone Meter, the MTM301 Blood Glucose Test Strips, and the MTM301 Blood Ketone test strips.

The MTM301 Blood Glucose and Ketone Monitoring System is intended to quantitatively measure blood glucose or blood ketone in fresh capillary whole blood drawn from fingertips. The system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control and should only be used by a single patient and it should not be shared. It is not intended for diagnosis or screening of diabetes or for neonatal use.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

- Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.
- Inaccurate results may occur in:
    - Severely hypotensive individuals
    - Patients in shock
    - In a hyperglycemic-hyperosmolar state with or without ketosis
- Do not use on critically ill patients.
- Do not use on neonates
- Do not use the system above 10,335 feet (3,150 meters) in altitude.
- Do not use if hematocrit exceeds the acceptable range between 20% to 60% when testing.
- Severe dehydration (excessive water loss) may cause inaccurate results.
- For In Vitro Diagnostic use only.
- For Over-the-Counter use only
- For single-patient use only.
- The system is not intended for diagnosis or screening of diabetes.
- The MTM301 blood glucose and MTM301 blood ketone test strip are not intended for alternative site testing (AST).

D Special Instrument Requirements:

MTM30l Blood Glucose and Ketone Meter

IV Device/System Characteristics:

A Device Description:

The MTM301 Blood Glucose and Ketone Monitoring System consists of the MTM301 Blood Glucose and Ketone Meter, MTM301 Blood Glucose test strips, MTM301 Blood Ketone test strips, MTM301 Glucose Control Solutions (Level 1 and Level 2), and MTM301 Ketone Control Solutions (Level 1 and Level 2) along with labeling and packaging. The control solutions and test strips can be purchased separately. The glucose and ketone test strips are the same, with the exception of the name, as previously cleared in k170267 and k182593, respectively.

B Principle of Operation:

The meter and test strips use biosensor technology. The glucose test strips contain an enzyme (glucose oxidase) that reacts to glucose present in blood, releasing electrons. The ketone test strips contain an enzyme (D-3-hydroxybutyrate dehydrogenase) that reacts to ketone present in blood, releasing electrons. The meter applies a small electrical current to the test strip and measures changes in the current caused by the reaction of glucose or ketone in the blood sample to the enzyme in the test strip. The meter converts the measured current into blood glucose or ketone reading that is displayed on the meter's liquid crystal display. Both glucose and ketone test strips are plasma-calibrated.

C Instrument Description Information:

1. Instrument Name:

   MTM301 Blood Glucose and Ketone Meter

2. Specimen Identification:

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

3. Specimen Sampling and Handling:

   The glucose and ketone system is intended to be used with capillary whole blood from the finger only. The whole blood sample is applied directly to the test strip by capillary action.

4. Calibration:

   The meter does not require calibration or coding by the user. The meter is automatically coded.

5. Quality Control:

MTM301 Glucose Control Solutions (Level 1 and Level 2) and MTM301 Ketone Control Solutions (Level 1 and Level 2) are available for use with the system. Each test strip vial is marked with a control solution range (CTRL1 and CTRL2). The user is instructed to compare the control results with the expected control ranges printed on the strip vial. Users are given instructions on when to conduct control solution testing and to call customer service if repeat testing with control material is out of range. The use will need to switch the meter manually to control testing mode prior to the application of control solution. Control solution testing results will be stored into the meter's memory and indicated with "ctl" icon and will not be used for calculating blood result averages.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Nova Max Plus Blood Glucose and β-Ketone Monitoring System

B Predicate 510(k) Number(s):

K091547

C Comparison with Predicate(s):

Device & Predicate Device(s):	K202534	K091547
Device Trade Name	MTM301 Blood Glucose and Ketone Monitoring System	Nova Max Plus Blood Glucose and β-Ketone Monitoring System
General Device Characteristic Similarities		
Intended Use	Quantitatively measure blood glucose or blood ketone in fresh capillary whole blood drawn from fingertips. The system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control.	Same

Device & Predicate Device(s):	K202534	K091547
Glucose measuring range	20-600 mg/dL	Same
Ketone measuring range	0.1 – 8.0 mmol/L	Same
Glucose Test Strips Active reagent:	glucose oxidase	Same
Ketone Test Strips Active reagent	β-hydroxybutyrate dehydrogenase	Same
General Device Characteristic Differences		
Battery	2 × CR2032, 3 volt coin cell battery	3 volt coin cell battery CL2450
Operation Condition	10°C - 40°C (50-104°F), 20~90% RH	14°C - 40°C 10~90% RH
Hematocrit Range	20%-60%	25%-60%
Sample size	0.5 µL glucose 0.8 µL ketone	0.3 µL glucose 0.8 µL ketone

VI Standards/Guidance Documents Referenced:

CLSI EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition

IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Glucose Within-run Precision
The sponsor performed a within-run precision study to assess the glucose functionality of the MTM301 Blood Glucose and Ketone Monitoring System using venous blood samples spiked to achieve 5 glucose concentrations (30-50, 51-110, 111-150, 151-250, 250-400 mg/dL). Each glucose level was analyzed in replicates of 10, with 3 test stirp lots, and 10 meters for a total of 300 tests per each glucose level. Results are summarized below:

Venous Blood Glucose Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	CV
Level 1	Lot 1	100	45	1.9	4.3%
	Lot 2	100	45	1.9	4.2%
	Lot 3	100	45	1.9	4.3%
	Combined	300	45	1.9	4.3%
Level 2	Lot 1	100	89	2.1	2.4%
	Lot 2	100	90	2.1	2.3%
	Lot 3	100	89	2.4	2.7%
	Combined	300	89	2.2	2.5%
Level 3	Lot 1	100	119	3.1	2.6%
	Lot 2	100	119	3.2	2.7%
	Lot 3	100	120	3.4	2.8%
	Combined	300	119	3.2	2.7%
Level 4	Lot 1	100	220	5.0	2.3%
	Lot 2	100	220	5.0	2.3%
	Lot 3	100	220	4.7	2.1%
	Combined	300	220	4.9	2.2%
Level 5	Lot 1	100	330	7.6	2.3%
	Lot 2	100	331	7.1	2.1%
	Lot 3	100	330	7.5	2.3%
	Combined	300	330	7.4	2.2%

Glucose Intermediate Precision:
Intermediate precision of the MTM301 Blood Glucose and Ketone Monitoring System was evaluated using 5 levels of glucose control solutions (30-50, 51-110, 111-150, 151-250, 251-400 mg/dL) using 3 lots of MTM301 Blood Glucose test strip was performed. Each sample was measured using 10 MTM301 meters over ten days for a total of 300 glucose results per each glucose level. Results are summarized below:

Control Levels	Strip lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	Lot 1	100	41	0.7	1.7%
	Lot 2	100	40	1.0	2.6%
	Lot 3	100	40	0.9	2.3%
	Combined	300	40	0.9	2.2%
Level 2	Lot 1	100	70	0.9	1.3%
	Lot 2	100	70	0.7	1.0%
	Lot 3	100	68	1.1	1.6%
	Combined	300	69	1.2	1.8%

Control Levels	Strip lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 3	Lot 1	100	121	0.6	0.5%
	Lot 2	100	121	1.2	1.0%
	Lot 3	100	121	0.8	0.6%
	Combined	300	121	0.9	0.7%
Level 4	Lot 1	100	222	1.0	0.4%
	Lot 2	100	222	1.1	0.5%
	Lot 3	100	222	1.1	0.5%
	Combined	300	222	1.0	0.5%
Level 5	Lot 1	100	328	1.7	0.5%
	Lot 2	100	328	1.7	0.5%
	Lot 3	100	332	2.8	0.8%
	Combined	300	329	2.8	0.9%

Ketone Test Strip

The ketone precision performance was previously established in k182593.

2. Linearity:

The linearity of the glucose measurement function of the MTM301 Blood Glucose and Ketone Monitoring System was evaluated using venous whole blood spiked with glucose. Eleven whole blood samples were adjusted to the following glucose concentration ranges (as measured by YSI 2300): 19.7, 50.1, 80.7, 115, 160, 200, 260, 310, 420, 530 and 610 mg/dL. Each level was measured using 3 test strip lots and the results compared with those obtained from the YSI 2300. The summary of the linear regression analysis for each lot was as follows:

Test Strip Lot #	**Slope**	**y-intercept**	**R^2 value**
Lot 1	1.0038	-0.5982	0.9995
Lot 2	1.0009	-0.4580	0.9995
Lot 3	0.9999	0.0542	0.9995

The results of the study support the sponsor's claimed glucose measuring range of 20-600 mg/dL.

Ketone linearity was previously established in k182593.

Validation testing was performed demonstrating that the meter displays an alternate flashing "Ket" icon and 'HI" when the ketone measurement result is greater than 8.0 mmol/L and an alternate flashing "Ket" icon with "LO" when the ketone measurement result is less than 0.1 mmol/L as intended.

Validation testing was performed demonstrating that the meter displays a static "HI" when the glucose measurement result is greater than 600 mg/dL and a static "LO" when the glucose measurement result is less than 20 mg/dL.

3. Analytical Specificity/Interference:

Previously established in k141036 for glucose and in k182593 for ketone.
The sponsor includes the following limitations in the labeling for the MTM301 Blood Glucose and Ketone Monitoring System:

- If you are taking acetaminophen or acetaminophen containing drugs (for example Tylenol; at blood concentrations > 10 mg/dL) you may get inaccurate results with this system.
- If you are taking Tolbutamide at blood concentrations > 15 mg/dL, you may get inaccurate results with this system.
- If you are taking Ibuprofen or Ibuprofen containing drugs as Advil at blood concentrations > 40 mg/dL, you may get inaccurate results with this system
- If you are taking Paralidoxime Iodide (PAM) or Paralidoxime Iodide (PAM) containing drugs at blood concentrations > 50 mg/dL, you may get inaccurate results with this system.
- If you have a disease or condition in which uric acid levels in your blood may be elevated (>15 mg/dL), such as gout, you may get inaccurate results with this system.
- Do not use during or soon after xylose absorption testing since xylose may cause inaccurate glucose results. Ask your doctor how long to wait before performing a glucose test.

4. Assay Reportable Range:

20 - 600 mg/dL for Glucose
0.1 - 8.0 mmol/L for Ketone

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Traceability

The glucose measurement functionality of the MTM301 Blood Glucose and Ketone Monitoring System is traceable to the NIST SRM 917b glucose reference material. The method comparison/lay-user study was performed using the YSI 2300 Glucose Analyzer as the comparator method (see section VII.C.3).

The ketone measurement functionality of the MTM301 Blood Glucose and Ketone Monitoring System is traceable to in-house standards prepared from commercially available control materials. The method comparison/lay user study was previously performed (k182593) using STANBIO ß-Hydroxybutyrate assay on the Beckman Coulter AU480 as the comparator method.

Test Strip Stability

Protocols and acceptance criteria for the shelf-life and open vial stability for the MTM301 Blood Glucose Test Strips were previously evaluated in k141036 and found to support the claimed shelf life of 24 months when stored under conditions of 39-86°F and a relative humidity of 10-85% and a 6 month open vial claim when stored under these same conditions.

Shelf-life for the individually wrapped MTM301 Blood Glucose Test Strips was assessed using real-time testing. The study protocols and acceptance criteria were reviewed and found acceptable to support the sponsor's claimed shelf-life stability of 24 months when stored at recommended storage conditions of 39-86°F (10-30°C) and 10-85% relative humidity.

Shelf-life and open vial stability for the MTM301 Ketone Test Strips were evaluated using real-time testing. Study protocols and acceptance criteria were reviewed and found acceptable to support the sponsor's claimed shelf life of 18 months when stored at the recommended storage conditions of 39-86°F (10-30°C) and 10-85% relative humidity and an open vial stability of 3 months when stored under these same conditions.

Protocols and acceptance criteria for the shelf -life for the individually wrapped MTM301 Ketone Test Strips was previously evaluated in k182593 to support the claimed shelf life of 18 months when stored under conditions of 39-86°F and a relative humidity of 10-85%.

6. Detection Limit:

   Please see Section VII.A.2 for glucose and refer to k182593 for ketone.

7. Assay Cut-Off:

   Not applicable.

8. Accuracy (Instrument):

   Not applicable.

9. Carry-Over:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Please refer to lay user study below in section VII.C3.

2. Matrix Comparison:

Not applicable. The device is only intended for use with fresh capillary whole blood from a fingerstick.

C Clinical Studies:

1. Clinical Sensitivity:

Not Applicable.

2. Clinical Specificity:

Not Applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Glucose method comparison/lay user performance study:
To assess the performance of the glucose functionality of the MTM301 Blood Glucose and Ketone Monitoring System in the hands of the intended users, the sponsor performed a study with 350 lay-user participants. The users were responsible for obtaining their own fingertip capillary sample and performing a blood glucose test according to the instructions in the labeling. A total of 15 MTM301 Blood Glucose and Ketone meters and 3 lots of MTM301 Blood Glucose Test Strip were used. Results were analyzed by comparing the blood glucose results obtained by the lay users with the MTM301 Blood Glucose and Ketone Monitoring System against results obtained with the laboratory-based comparator method (YSI 2300 glucose analyzer). The glucose concentrations in the samples ranged between 63-494 mg/dL, as measured by the YSI 2300 glucose analyzer. The samples included 16 native samples with glucose concentration < 80 mg/dL and 131 samples with glucose concentration > 250 mg/dL. The results compared to YSI 2300 glucose analyzer are summarized below:

For glucose concentrations <75 mg/dL				
Sample Site	within± 5 mg/dL	within± 10 mg/dL	within± 15 mg/dL	within± 20 mg/dL
Fingertip	4/10 (40%)	10/10 (100%)	10/10 (100%)	10/10 (100%)

For glucose concentrations ≧75 mg/dL				
Sample Site	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Fingertip	158/340 (46.3%)	311/340 (91.7%)	340/340 (100%)	340/340 (100%)

System Accuracy Results for Entire Glucose range				
Sample Site	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Fingertip	162 / 350 (46.3%)	321 / 350 (91.7%)	350 / 350 (100%)	350 / 350 (100%)

Results of linear regression analysis: $y = 1.0091x - 1.9847$, $R^2 = 0.9785$

Usability Assessment:
The usability of the system was assessed by questionnaires given to the operators of the system following the conclusion of the glucose and ketone lay user studies where the participants read the labeling documents without any assistance or guidance. The study participants then independently completed meter setup, performed glucose/ketone measurement using blood/control and retrieved/marked the test results in the same way as home users. The study participants were asked to complete a usability questionnaire regarding ease of understanding of information in the user manual and the ease of use when performing a blood ketone test. The study demonstrated that users could use the combined glucose and ketone device with ease and are able to interpret the different results and messages/errors appropriately under different user scenarios.

From the sponsor's analysis of the questionnaire responses, the participants overall were satisfied with the ease of operation by following the instructions for use in the User's Manual and the overall performance of the MTM301 Blood Glucose and Ketone Monitoring System.

Accuracy at Extreme Glucose Study:
A study to evaluate the performance of MTM301 Blood Glucose and Ketone Monitoring System in the extreme lower and upper ends of the claimed range was performed using 50 whole blood samples that were allowed to glycolyze to achieve glucose concentrations below 80 mg/dL (22-79 mg/dL), and 50 whole blood samples that were spiked to achieve glucose concentrations greater than 250 mg/dL (256-590 mg/dL). Results on the candidate device using 3 test strip lots were compared to the results obtained using the comparator method (YSI 2300 glucose analyzer). Results are summarized below:

System accuracy results for extreme low (<80mg/dL) glucose readings			
Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
17/50 (34%)	42/50 (84%)	50/50 (100%)	50/50 (100%)
System accuracy results for extreme high (>250mg/dL) glucose readings			
Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
33/50 (66%)	48/50 (96%)	50/50 (100%)	50/50 (100%)

Labeling Readability
The readability of the over-the counter, home use labeling was evaluated using a Flesch-Kincaid analysis and demonstrated that the grade level scores were less than 8th grade.

D Clinical Cut-Off:

Not Applicable.

E Expected Values/Reference Range:

Based on published literature, the sponsor included the following in the labeling:

Glucose[1]

The expected glucose values for adults without diabetes are:
- Under 100 mg/dL fasting.
- Under 140 mg/dL two hours after meals.

Ketone[2]

The normal adult blood β-Ketone range for a person without diabetes is less than 0.6 mmol/L.

1. American Diabetes Association, Standard of Medical Care in Diabetes 2020, Vol. 43 (Suppl. 1).
2. Tietz NW. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia, PA: WB Saunders Company; 4th Edition.

F Other Supportive Instrument Performance Characteristics Data:

Flex Studies:
Studies were performed to assess the effect of the following measurement functions of the candidate system: used test strip insertion, test strip removal during measurement countdown, intermittent sampling, sample perturbation, and dropping. The testing demonstrated that the MTM301 Blood Glucose and Ketone Monitoring System is robust to these use scenarios and that either an error message is returned, or an accurate result is displayed.

Operating Conditions:
The effect of operating temperatures and relative humidity on the performance of the MTM301 Blood Glucose and Ketone Monitoring System was evaluated using venous whole blood samples adjusted to approximately 60, 120, 200, 400 mg/dL and 3 levels of glucose control solution. Testing was conducted under the following temperature and relative humidity (RH) combinations: 10°C / 20% RH low temperature, low humidity); 10°C / 90% RH (low temperature, high humidity); 40°C / 10% RH (high temperature, low humidity); 40°C / 90% RH (high temperature, high humidity), and 24°C / 50% RH (nominal). Glucose results obtained under these conditions was collected using 10 MTM301 meters and three lots of test strips and results were compared to the nominal condition (25°C / 50% RH). The study results support the claimed operating conditions of 10° to 40°C (50°F to 104°F) with relative humidity of 10% to 90%.

Disinfection (Robustness) Testing
This device system is for single patient use only. Disinfection efficacy studies were previously performed (k141036) on the exterior meter materials by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Clorox Healthcare Bleach Germicidal Wipes (EPA Registration # 67619-12). Robustness studies were also performed by the sponsor demonstrating that there was no change in ketone or glucose performance or external materials of the meter after 260 cleaning and disinfection steps with the Clorox Healthcare Bleach Germicidal wipes. The robustness studies were designed to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

Hematocrit:
Previously established in k141036 and k182593 to support the claimed hematocrit range of 20-60% for glucose and ketone testing, respectively.

Altitude:
Previously established in k141036 and k182593 to support the use of the device up to 10,335 ft. (3150 meters) for both glucose and ketone testing.

Electromagnetic Compatibility (EMC):
EMC and electrical safety testing were previously provided (k182593).

Sample Volume:
The minimum sample volumes were previously established to support a 0.5 µL sample volume for glucose (k141036) and 0.8 µL sample volume for ketone (k182593).

Glucose Test Strip Lot Release Protocol:
Glucose test strip lot release protocols and criteria were reviewed and found to be acceptable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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