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

I Background Information:

A 510(k) Number

k193340

B Applicant

MicroTech Medical, Inc.

C Proprietary and Established Names

GoChek Blood Glucose Monitoring System
GoChek Connect Blood Glucose 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

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Glucose in capillary whole blood obtained from the fingertip

C Type of Test:

Quantitative, amperometric measurement of glucose.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The GoChek Blood Glucose Monitoring System
The GoChek Blood Glucose Monitoring System comprises of the GoChek Blood Glucose Meter and GoChek Blood Glucose Test Strips. The GoChek Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips. The GoChek Blood Glucose Monitoring System is intended for self-testing by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control programs. The GoChek Blood Glucose Monitoring System is intended for single-patient use and should not be shared.

The GoChek Blood Glucose Monitoring System is for in vitro diagnostic use. The GoChek Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes.

The GoChek Connect Blood Glucose Monitoring System
The GoChek Connect Blood Glucose Monitoring System comprises of the GoChek Connect Blood Glucose Meter and GoChek Blood Glucose Test Strips. The GoChek Connect Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips. The GoChek Connect Blood Glucose Monitoring System is intended for self-testing by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control programs. The GoChek Connect Blood Glucose Monitoring System is intended for single-patient use and should not be shared.

The GoChek Connect Blood Glucose Monitoring System is for in vitro diagnostic use. The GoChek Connect Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes.

C Special Conditions for Use Statement(s):

- OTC - Over The Counter
- This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. 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.
- This meter can only be used to determine blood glucose levels using whole blood samples from fingertips.
- For in vitro diagnostic use.
- For single-patient use only.

- This system should not be used for the diagnosis of or screening for diabetes.
- This system is not for use on patients with abnormally low blood pressure or those who are in shock.
- Test results may be lower than the actual values or inaccurate if the individual is hypotensive, in a hyperglycemic-hyperosmolar state (with or without ketosis).
- This system is not for use with neonates.
- This system should not be used on critically ill patients.
- This system should not be used on patients with impaired peripheral circulation or severe dehydration.
- Altitudes above 10,000 feet may cause inaccurate results.

D Special Instrument Requirements:

The GoChek Blood Glucose Meter
The GoChek Connect Blood Glucose Meter

IV Device/System Characteristics:

A Device Description:

GoChek/GoChek Connect Blood Glucose Monitoring System consists of a glucose meter (GoChek or GoChek Connect Blood Glucose Meter), GoChek Blood Glucose Test Strips (sold in vials of test strips and individually wrapped pouches of test strips; sold separately), carrying case, lancing device, batteries, and two levels of control solution (sold separately). The only difference between the GoChek and GoChek Connect meters is that the GoChek Connect meter has Bluetooth connectivity enabled.

B Principle of Operation:

The GoChek and GoChek Connect Blood Glucose meters measure the glucose concentration in capillary whole blood. Blood is applied to the end tip of the test strip. The blood is then automatically absorbed into the reaction cell. The reaction takes place in the reaction cell. The enzyme used is a Flavin-Adenine-Dinucleotide-Dependent Glucose Dehydrogenase (FAD-GDH). FAD-GDH oxidizes glucose to gluconolactone (GDL) and a transient electrical current is formed during the reaction which is detected by the meter. The blood glucose concentration is then calculated based on the electrical current. The result is then shown on the meter display in mg/dL for the user. The meters are calibrated to display plasma equivalent results.

C Instrument Description Information:

Modes of Operation	Yes	No
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☒	☐

Modes of Operation	Yes	No
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

1. Instrument Name:

   GoChek Blood Glucose Monitoring System
   GoChek Connect Blood Glucose Monitoring System

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:

   Samples are to be tested immediately upon collection.

4. Calibration:

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

5. Quality Control:

   The sponsor manufactures two (2) levels of GoChek control solutions. 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 meter automatically detects that a control solution is being used. When a control solution test is performed, the test results will not be included in the 'day average' calculation.

V Substantial Equivalence Information:

A Predicate Device Name(s):

On Call Sharp Blood Glucose Monitoring System

B Predicate 510(k) Number(s):

k130284

C Comparison with Predicate(s):

Device & Predicate Device(s):	K193340	K130284
Device Trade Name	GoChek Blood Glucose Monitoring System GoChek Connect Blood Glucose Monitoring System	On Call Sharp Blood Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the quantitative measurement of glucose in fresh capillary whole blood from the fingertips as an aid in monitoring the effectiveness of diabetes control programs.	Same
Assay Method	Electrochemical	Same
Detection Method	Amperometry	Same
Enzyme	Glucose Dehydrogenase (FAD-GDH)	Same
General Device Characteristic Differences		
Sample Type	Fresh capillary whole blood from the fingertips.	Fresh capillary whole blood from fingertips, forearm and palm
Hematocrit Range	10-70%	25-70%
Operating Temperature	41-113°F (5-45°C)	50-113°F (10-45°C)

VI Standards/Guidance Documents Referenced:

- ISO 14971:2007: Medical devices - Application of risk management to medical devices
- Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use: Guidance for Industry and Food and Drug Administration Staff, October 11th, 2016
- CLSI EP06-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline
- CLSI EP07-A2: Interference Testing in Clinical Chemistry; Approved Guideline Second Edition

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

Unless otherwise noted, the analytical studies detailed below were performed with the GoChek Blood Glucose Monitoring System, which is identical to the GoChek Connect Blood Glucose Monitoring System with the exception of the presence of Bluetooth in the GoChek Connect System. Therefore, the analytical studies performed with the GoChek Blood Glucose Monitoring System are representative of the performance for both systems in this 510(k) submission.

1. Precision/Reproducibility:

Within-Run Precision

The sponsor performed a repeatability study (within day) precision study using venous whole blood adjusted to five different glucose concentration ranges (30-50, 51-110, 111-150, 151-250, and 251-400 mg/dL). Each glucose concentration was analyzed in replicates of 10 with three test strips lots, and 10 meters, for a total of 100 tests per glucose level. Results are summarized in the table below:

Glucose Level	Average	SD	CV
1	35.3	1.88	5.3%
2	95.8	2.81	2.9%
3	128.3	3.74	2.9%
4	221.4	6.31	2.8%
5	382.9	10.05	2.6%

Intermediate Precision

Intermediate (day-to-day) precision was performed using five ranges of glucose control solution concentrations (30-50, 51-110, 111-150, 151-250, and 251-400 mg/dL). Testing was performed for 10 days with three test strip lots. For each level, on each day, 10 meters were used for testing, with one replicate collected per meter for a total of 10 replicates per day for each control solution level, for a total of 100 tests per control solution level. Results are summarized below:

Glucose Level	Average	SD	CV
1	37.5	1.61	4.3%
2	77.5	2.27	2.9%
3	128.0	3.01	2.4%
4	193.0	3.71	1.9%
5	346.7	7.07	2.0%

2. Linearity:

Linearity testing was evaluated with test strips from three lots and 11 mixed pools of venous whole blood samples with glucose concentrations of 7.5, 25.2, 43.7, 72.6, 95.5, 152.5, 199.5, 252.0, 300.0, 405.5, 511.5, and 578.0 mg/dL as measured with the YSI Model 2300 STAT

PLUS glucose analyzer. Each level was measured in replicates of four and the values obtained on the GoChek Blood Glucose Monitoring System were compared to the comparator. Linear regression analysis of the results yielded the following:

Lot	Slope	y-intercept	R^2
1	0.9960	-4.4024	0.9997
2	0.9743	-0.9445	0.9997
3	0.9949	-3.1076	0.9996

The results of the study support the sponsor's claimed glucose measuring range of 10 – 580 mg/dL. If a sample is less than 10 mg/dL, the result is flagged by the meter as LO. If the result is greater than 580 mg/dL, the result is flagged by the meter as HI. This low and high functions were validated and demonstrated to function as intended.

3. Analytical Specificity/Interference:

Interference testing was conducted using venous whole blood adjusted to a hematocrit of 42% ± 2% and glucose was adjusted to the following levels: 50 – 70 mg/dL, 110 – 130 mg/dL and 250 – 270 mg/dL. Control blood samples were prepared by adding solvent with no interferant. Control and test samples were measured using 10 strips on each of 2 meters using 3 strip lots. The highest tested concentrations at which no significant interference was observed (defined by the sponsor as average % bias $\leq \pm 10\%$) are presented in the following table:

Substances	Highest concentration testing with no significant interference
Acetaminophen	20 mg/dL
Ascorbic Acid	3 mg/dL
Cholesterol	500 mg/dL
Conjugated-Bilirubin	50 mg/dL
Creatinine	15 mg/dL
Dopamine	20 mg/dL
EDTA	200 mg/dL
Galactose	100 mg/dL
Gentisic acid	10 mg/dL
Glutathione Reduced	92 mg/dL
Hemoglobin	2000 mg/dL
Heparin Sodium	80000 u/L
Ibuprofen	50 mg/dL
Icodestrin	1094.4 mg/dL
Isomalt	0.09 mg/dL
L-Dopa (Levo-Dopa)	3 mg/dL
Lactitol	0.09 mg/dL
Maltitol	0.09 mg/dL
Maltose	9000 mg/dL
Mannitol	0.09 mg/dL
Methyl Dopa	1.5 mg/dL

Substances	Highest concentration testing with no significant interference
Paralidoxime Idodine (PAM)	80 mg/dL
Salicylic Acid	60 mg/dL
Sodium	414 mg/dL
Sorbitol	0.09 mg/dL
Tolazamide	10 mg/dL
Tolbutamide	64 mg/dL
Triglycerides	3000 mg/dL
Uric Acid	24 mg/dL
Xylitol	0.09 mg/dL
Xylose	40 mg/dL

The sponsor includes the following in the labeling for the GoChek and the GoChek Connect Blood Glucose Monitoring Systems:

- If you are taking Vitamin C (ascorbic acid, blood concentrations >3 mg/dL) at doses higher than recommended, it may interfere with your glucose meter and cause you to get inaccurate results with this system.
- Do not use this system during or shortly after receiving xylose absorption therapy; xylose may case inaccurate blood glucose results.

4. Assay Reportable Range:

Assay reportable range, 10 - 580 mg/dL.

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

The system is traceable to NIST SRM 917b glucose reference material. A method comparison was performed using the candidate device and YSI Model 2300 STAT PLUS glucose analyzer as the comparator method.

Test Strip Stability:

Test strip (vials and individually wrapped pouches of strips) stability was assessed using accelerated and real time stability studies. Protocols and acceptance criteria were reviewed and found acceptable to support the labeling claims that vialed test strips are stable for 6 months after first being opened and vialed and individually wrapped pouches are stable for 3 years when stored between of 35.6ºF to 95ºF (2ºC-35ºC) and 10-90% relative humidity.

6. Detection Limit:

The claimed reportable range for this assay is 10-580 mg/dL.

7. Assay Cut-Off:

Not applicable.

8. Accuracy (Instrument):

   Not applicable.

9. Carry-Over:

   Not applicable. The device uses single-use strips.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   See lay user study below, section VII.C3, for system accuracy in the hands of the intended user.

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):

   Lay-user Performance study:

   To assess the performance of the GoChek Connect Blood Glucose Monitoring System in the hands of the intended users, the sponsor performed studies with 360 English speaking participants. The participants were responsible for obtaining their own fingertip capillary sample and performing a blood glucose test using only the instructions from the product labeling. A total of 360 meters and 20 test strip vials, each containing 25 test strips, from 3 test strip lots were used. The glucose concentrations across all samples ranged from 42.2 to 420.1 mg/dL, which includes 34 native samples < 80 mg/dL and 37 samples > 250 mg/dL as measured by the comparator method. Results were analyzed by comparing the blood glucose results obtained by the lay users with the GoChek Connect Blood Glucose Monitoring System against results obtained with a laboratory-based comparator method (YSI Model 2300 STAT PLUS glucose analyzer). The glucose concentrations in the samples ranged from 42.2-420.1 mg/dL, as measured by the YSI Model 2300 STAT PLUS glucose analyzer. Results are summarized in the tables below:

For glucose concentrations < 75 mg/dL:			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	Within ± 20 mg/dL
21/25 (84.0%)	25/25 (100%)	25/25 (100%)	25/25 (100%)

For glucose concentrations > 75 mg/dL:			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
165/335 (49.3%)	269/335 (80.3%)	329/335 (98.2%)	335/335 (100%)

Combined glucose concentrations across the measuring range:			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
176/360 (48.9%)	289/360 (80.3%)	353/360 (98.1%)	360/360 (100%)

Accuracy at Extreme Glucose Study:
An additional accuracy study was performed by testing 240 capillary fingerstick whole blood samples containing glucose concentrations from 12.5 to 584.3 mg/dL. Samples were altered by spiking or glycolysis to obtain 120 samples with glucose <80 mg/dL, ranging from 12.5 to 79 mg/dL, and 120 samples with glucose concentrations >250 mg/dL, ranging from 251 to 584.3 mg/dL. Samples obtained using the GoChek Connect Blood Glucose Monitoring System were compared to the results obtained on the comparator method (YSI 2300 STAT PLUS). Results are summarized in the tables below:

For glucose concentrations < 80 mg/dL:			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
40/120 (39.2%)	92/120 (76.7%)	117/120 (97.5%)	120/120 (100%)

For glucose concentrations >250 mg/dL:			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
46/120 (38.3%)	92/120 (76.7%)	117/120 (97.5%)	119/120 (99.2%)

Readability:
The user manual and inserts were assessed for readability using the Flesch-Kincaid's assessment and it was observed that the overall readability level was as that of an 8th grader.

D Clinical Cut-Off:

Not Applicable

E Expected Values/Reference Range:

The following expected glucose values for people without diabetes are included in the device labeling:

Time	Range, mg/dL	Range, mmol/L
Fasting and Before Meals	70 – 100	3.9 – 5.6
2 Hours After Meal	Less than 140	Less than 7.8

Source: Standards of Medical Care in Diabetes - 2020, Diabetes Care 2020 Jan; 43 (Supplement 1): S1-S2.

F Other Supportive Instrument Performance Characteristics Data:

1. Altitude Study

   To evaluate the effect of altitude on the GoChek Blood Glucose Monitoring System, a study was conducted using venous whole blood samples adjusted with four concentration levels of glucose ranging from 40-500 mg/dL. Samples were tested at two different altitude conditions at sea level (65 feet) and 11,410 feet. Blood samples were tested using 10 test strips at each altitude condition for each glucose concentration. Eighty test strips from 3 lots were used. The results obtained on the candidate device were compared with the results obtained with the comparator method, YSI 2300 STAT PLUS glucose analyzer. The results demonstrated acceptable bias to the comparator to support the claim in the labeling that glucose measurement performance of the GoChek Blood Glucose Monitoring System is maintained at altitudes up to 10,000 feet.

2. Hematocrit

   To evaluate the effect of hematocrit on the GoChek Blood Glucose Monitoring System, venous blood samples were adjusted to hematocrit levels of 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%. Each hematocrit level was adjusted to achieve five glucose concentration ranges (30-50 mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, and 251-400 mg/dL). Blood samples were tested using the GoChek meter with test strips from three lots and the mean glucose values were compared to the results obtained on the comparator method, YSI 2300 STAT PLUS glucose analyzer. The percent biases relative to the comparator method demonstrated were acceptable to support the claimed hematocrit range of 10 to 70%.

3. Operating Conditions

   The effect of temperature and relative humidity on the GoChek Blood Glucose Monitoring System was evaluated using venous whole blood samples adjusted to approximately four glucose concentration ranges (40-50, 100-120, 250-300, and 500-550 mg/dL). Testing was conducted under the following temperature and relative humidity (RH) combinations: 5°C at 10% relative humidity (RH), 5°C at 90% RH, 21°C at 10% RH, 21°C at 90% RH, 21°C at 45% RH, 45°C at 10% RH and 45°C at 90% RH. Test strips from three lots were used to test the blood samples at each glucose concentration in 10 replicates of 10. Values were compared to results from the comparator method, YSI 2300 STAT PLUS glucose analyzer. The study results support the operating conditions claim of 41-113°F (5-45°C) with relative humidity of 10% to 90%.

4. Sample volume Study

   The sponsor performed a study to support the claimed minimum sample volume of 0.5 µL for the GoChek Blood Glucose Monitoring System. Venous whole blood samples

with three ranges of glucose concentrations (50-65, 100-120, 200-250 mg/dL) were tested at five sample volumes (0.3, 0.4, 0.5, 0.6, and 0.7 µL). Each sample was tested with 10 test strips from 3 lots. Values obtained were compared to the comparator method, YSI 2300 STAT PLUS. The meter has an error message that is displayed if insufficient blood is added to the test strip. This feature was validated and was shown to function as intended. The study results support the claimed sample volume of 0.5 µL.

5. Flex Studies

   The following additional flex studies were performed with the GoChek Blood Glucose Monitoring System: sample perturbation, sample outside measuring range, intermittent sampling, drop, vibration, and shipping testing were completed. The testing performed demonstrated that the device is robust under these conditions.

6. Infection Control Studies

   The two device systems, GoChek and GoChek Connect Blood Glucose Monitoring System, are intended for single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, CaviWipes (EPA Registration # 46781-8). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 7,665 cleanings and disinfection steps with the CaviWipes wipes. The robustness studies were designed to simulate 3 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

7. Electromagnetic Compatibility (EMC) Testing

   The sponsor provided documentation certifying that acceptable electrical safety and EMC testing had been performed and the system was found to be compliant.

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.