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

A. 510(k) Number:

k120921

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative, Amperometric method, Glucose oxidase

E. Applicant:

Simple Diagnostics, Inc.

F. Proprietary and Established Names:

CLEVER CHOICE (Four Models):

Clever Choice Voice+ S Blood Glucose Monitoring System

Clever Choice Voice+ M Blood Glucose Monitoring System

Clever Choice+ S Blood Glucose Monitoring System

Clever Choice+ M Blood Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
NBW – system, test, blood glucose, over the counter	Class II	21 CFR § 862.1345	75 - Chemistry
CGA – glucose oxidase, glucose	Class II	21 CFR § 862.1345	75 - Chemistry
JJX – Single Analyte control	Class I	21 CFR § 862.1660	75 – Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   Clever Choice Voice+ S Blood Glucose Monitoring System

   Clever Choice Voice+ S Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf and thigh. The Clever Choice Voice + S Blood Glucose Monitoring System is to be used by a single person and should not be shared.

   The Clever Choice Voice+ S Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Clever Choice Voice+ S Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

   The Clever Choice +S Blood Glucose Test Strips are for use with the Clever Choice Voice+ S Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.

   The Clever Choice Glucose Controls are intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the Clever Choice Voice+ S meters and Clever Choice +S test strips.

   The Clever Choice Voice+ M Blood Glucose Monitoring System

   The Clever Choice Voice+ M Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf and thigh. The Clever Choice Voice + M Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program.

The Clever Choice Voice + M Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing such as the palm, forearm, upper arm, calf and thigh should be done only during steady – state times (when glucose is not changing rapidly).

The Clever Choice +M Blood Glucose Test Strips are for use with the Clever Choice Voice +M Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.

The Clever Choice Glucose Controls are intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the Clever Choice Voice+ M meters and Clever Choice test strips.

Only auto-disabling, single use lancing devices may be used with this device.

The Clever Choice+ S Blood Glucose Monitoring System

The Clever Choice+ S Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf and thigh. The Clever Choice+ S Blood Glucose Monitoring System is to be used by a single person and should not be shared.

The Clever Choice+ S Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Clever Choice+ S Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The Clever Choice +S Blood Glucose Test Strips are for use with the Clever Choice+ S Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.

The Clever Choice Glucose Controls are intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the Clever Choice+ S meters and Clever Choice test strips.

The Clever Choice Voice+ M Blood Glucose Monitoring System

The Clever Choice Voice+ M Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf and thigh. The Clever Choice + M Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program.

The Clever Choice Voice+ M Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing such as the palm, forearm, upper arm, calf and thigh should be done only during steady – state times (when glucose is not changing rapidly).

The Clever Choice +M Blood Glucose Test Strips are for use with the Clever Choice+ M Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.

The Clever Choice Glucose Controls are intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the Clever Choice+ M meters and Clever Choice test strips.

Only auto-disabling, single use lancing devices may be used with this device.

3. Special conditions for use statement(s):
   - Clever Choice Voice+S, Voice+M, +S and +M Blood Glucose Monitoring Systems are for prescription use and over-the-counter (OTC) use
   - The multiple-patient use systems should only be used with auto-disabling, single-use lancing devices
   - The single patient use systems are for single-patient use only and should not be shared.
   - Not intended for use on neonates
   - Not for the diagnosis of or screening for diabetes mellitus
   - Alternative site testing (AST) should not be used to calibrate continuous glucose monitoring systems (CGMs)
   - Results from alternative site testing should not e used in insulin dose calculations.
   - Alternative site testing should be performed only during steady – state times (when glucose is not changing rapidly)

4. Special instrument requirements:
   Self-Testing glucose meter models:
   Clever Choice Voice+ S
   Clever Choice+ S

Multiple patient use glucose meter models:
Clever Choice Voice+ M
Clever Choice+ M

I. Device Description:

Clever Choice Voice+ S and Clever Choice+ S Blood Glucose Monitoring Systems (BGMS) consist of a blood glucose meter, single use test strips, sterile lancets, lancing device and the control solutions (level II included in the standard kit, Levels I and III are sold separately).
Clever Choice Voice+ M and Clever Choice +M Blood Glucose Monitoring Systems (BGMS) consist of a blood glucose meter, Clever Choice +M Blood Glucose Test Strips, Auto-disabling Lancing device and the control solutions (level II included in the standard kit, Levels I and III are sold separately).

The four blood Glucose Monitoring system models are all 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 5 seconds. The control solution available is used to test the performance of the device.

The test strips are identical to the strips previously cleared in k101307.

1. Predicate device name(s):

   AG-6951 Single Blood Glucose Monitoring System

   AG-6951 Multi Blood Glucose Monitoring System

2. Predicate K number(s):

   k101307

3. Comparison with predicate:

CHARACTERISTICS	**PREDICATE:** **AG-6951 Single and Multi Blood Glucose Monitoring System (k101307)**	**Clever Choice Voice+ S** **Clever Choice Voice+ M** **Clever Choice S** **Clever Choice M Single and Multi Blood Glucose Monitoring System**
Intended use	It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program.	Same
Detection Method	Amperometry	Same
Enzyme	Glucose Oxidase	Same
Setting	Single and Multiple patient use	Same
Sample Type	Capillary whole blood	Same
Sample Sites	Fingertip and AST	Fingertip, palm, forearm, upper arm, calf and thigh
Hematocrit Range	20-60%	Same
Operating Temperature	10ºC～40ºC(50°-104°F)	Same
Dimensions	52mmx 92mmx 21mm	102mm×58mm ×22mm
Display	LCD	Same
Result Presentation	mg/dL or mmol/L	Same
Memory Capabilities	500 times with time and date displaying	Same
Calibration Coding	No user coding required	Same
Sample Test Time	5 seconds	Same
Power Source	DC 3V (CR2032)	Same
Measurement Range	20mg/dL-600mg/dL	Same
Test Strips	AGS-1100 Test Strip	Clever Choice Test Strip
Sample Volume	Minimum 0.7 μL	Same
Other function	USB function. Voice function	USB function. Voice function (only on Voice+S and Voice+M models)

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

1. ISO 15197:2003(E) In Vitro Diagnostic Test Systems Requirements For Blood-Glucose Monitoring Systems

2. IEC 61010-1: 2001, Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements

3. IEC 61010-2-101: 2002, Particular requirements for in vitro diagnostic (IVD) medical equipment.

4. EN/IEC 61326-1:2006 Electrical equipment for measurement, control and laboratory use – EMC requirements part 1: General requirement.

5. EN/IEC 61326-2-6 Electrical equipment for measurement, control and laboratory use –EMC requirements Part 2-6: Particular requirements In vitro diagnostic (IVD) medical equipment

L. Test Principle:

The Clever Choice Voice+ S, Clever Choice Voice+ M, Clever Choice+ S (non-voice version), and Clever Choice+ M (non-voice version) glucose meters use glucose oxidase enzyme chemistry as the standard dry reagent assay for glucose in whole blood. This enzyme assay, with a redox chemical "mediator" reaction, is used to generate an electrical current proportional to the glucose concentration in the blood sample. The system is designed as an amperometric measurement device using current generated for the redox reaction as the measureable response.

M. Performance Characteristics (if/when applicable):

This submission encompasses four meter models. Given that all four meter models are identical with the exception of two meters including a voice function (Voice+ S and Voice+M models), only one set of performance data is provided throughout the submission.

1. <u>Analytical performance:</u>

   a. Precision/Reproducibility:

   Within-run precision was measured by using heparinized venous whole blood as the anti-coagulant at five different glucose concentrations. Each sample was tested on 3 lots of test strips on 10 meters (two meters assigned to each operator). Ten replicates were tested per meter, test strip lot, and glucose concentration, (N=100 per test strip). Results are summarized below:

Glucose (mg/dL)	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	100	44.0	2.6	5.94
51-110	100	98.0	3.5	3.55
111-150	100	128.	3.8	3.00
151-250	100	211.	6.8	3.23
251-400	100	356.	11.2	3.13

Between-day precision was measured by reading three different control materials on 3 lots of test strips, using 10 test strips on 10 meters (1 strip per meter), over 10 days (N=100 per test strip). Results are summarized below.

Control Solution Level	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Low (45 mg/dL)	100	44.5	2.5	5.58
Medium (120 mg/dL)	100	123.9	4.0	3.20
High (320 mg/dL)	100	310.8	8.8	2.82

b. *Linearity/assay reportable range:*
Eleven venous (heparin) whole blood samples were drawn and spiked to target analyte levels using glucose stock solutions to glucose concentrations ranging from 20-600 mg/dL (20.1, 34.6, 91.4, 165, 220, 275, 359, 420, 501, 574, and 601mg/dL). All samples were also tested on a YSI analyzer to generate the expected values The observed values were plotted against an average of the expected values and an appropriate line fitted by standard linear regression was generated of y=.9858x+5.1294 and an r^2 = 0.9995.
The claimed measuring range for this device is 20 to 600 mg/dL.

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

Traceability:

The sponsor claims that the system accuracy of the Clever Choice Voice+ S, Clever Choice Voice+ M, Clever Choice+ S, and Clever Choice+ M blood glucose monitoring systems are traceable to the YSI 2300 reference material. The method comparison study was performed using the candidate device and the YSI as the reference method.

Control Solutions and Test Strips identical to those cleared in k101307. As such, please see k101307 for traceability, stability, and expected value information.

d. *Detection limit:*
The reportable range is 20 to 600 mg/dL based on linearity/reportable range studies above (section M.1.b.).

e. Analytical specificity:

The test strips for this submission are the same as those cleared in k101307 with changes to the dimensions of the meter and the addition of alternate site testing. Please see k101307 for information regarding analytical specificity for this test system.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

System accuracy study:

The system accuracy study was performed with 100 fresh capillary blood samples collected from volunteers at two different hospitals and measured by 2 health care professionals on two different Clever Choice auto code voice + meters and using 3 lots of test strips. An aliquot of each sample collected was measured on a YSI reference method analyzer in order to evaluate the accuracy of the candidate meters. To obtain blood glucose concentrations <50 mg/dL and > 400 mg/dL, samples were allowed to glycolyze or were spiked to achieve the desired glucose concentrations. The range of samples tested was 24.8 –542 mg/dL. System accuracy results are summarized below:

Meter 1 vs. YSI-2300 reference Method

slope	1.0561
Y-intercept	-3.2796
R square	0.992

System accuracy results for glucose concentrations < 75 mg/dL (Meter 1)

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
16/18 (89%)	18/18(100%)	18/18(100%)

System accuracy results for glucose concentrations >75 mg/dL (Meter 1)

Within ±5%	Within ±10%	Within ±15%	Within ±20%
45/82 (55%)	71/82 (86%)	81/82 (99%)	82/82(100%)

Meter 2 vs. YSI-2300 reference Method

slope	1.0453
Y-intercept	-2.5142
R square	0.9924

System accuracy results for glucose concentrations < 75 mg/dL (Meter 2)

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
16/18 (89%)	18/18 (100%)	18/18 (100%)

System accuracy results for glucose concentrations ≥75 mg/dL (Meter 2)

Within ±5%	Within ±10%	Within ±15%	Within ±20%
55/82 (67%)	75/82 (91%)	81/82 (99%)	82/82 (100%)

Alternative Site Testing:

In this study, capillary whole blood samples collected from 100 volunteers from the following sites: palm, forearm, upper arm, calf, and thigh. Two Clever Choice Auto-Code Choice + meters and 3 lots of test strips were used over the 10 day study period. Glucose results obtained using the meters were obtained by health care professionals and compared to results obtained using the YSI reference method. The range of glucose results tested was 51.8 – 398 mg/dL.

The following are a summary of results:

	Finger	Palm	Forearm	Upper arm	Calf	Thigh
Slope(comparison with YSI)	1.0346	1.0515	1.0203	1.0333	1.0445	1.0421
Y-Intercept(comparison with	-0.8642	-2.8173	0.1706	-2.7424	-4.8619	-4.9
R(comparison with YSI)	0.9916	0.9858	0.9832	0.9875	0.9747	0.9803

System accuracy results were presented separately for the glucose concentration interval < 75mg/dL and >75mg/dL in the following.

System accuracy results for glucose concentrations < 75 mg/dL

Difference range in values between the alternative sites value and the finger value	within ±5mg/dL	within ±10mg/dL	within ±15mg/dL
Palm	10/16 (63%)	15/16 (94%)	16/16(100%)
Forearm	8/16 (50%)	15/16 (94%)	16/16 (100%)
Upper Arm	10/16 (63%)	16/16 (100%)	16/16 (100%)
Calf	12/16 (75%)	15/16 (94%)	16/16 (100%)
Thigh	12/16 (75%)	15/16 (94%)	16/16 (100%)

System accuracy results for glucose concentrations ≥ 75 mg/dL

Difference range in values between the alternative sites'value	within ±5%	within ±10%	within ±15%	within ±20%
Palm	46/84 (55%)	73/84 (87%)	81/84 (96%)	82/84 (98%)
Forearm	36/84 (43%)	68/84 (81%)	79/84 (94%)	84/84 (100%)
Upper arm	41/84 (49%)	68/84 (81%)	80/84 (95%)	84/84 (100%)
Calf	36/84 (43%)	63/84 (75%)	80/84 (95%)	84/84 (100%)
Thigh	38/84 (45%)	65/84 (77%)	79/84 (94%)	83/84 (99%)

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):

Lay user performance study:
A user performance study was performed to compare lay user self test fingerstick and AST (palm, forearm, upper arm, calf, and thigh) to the YSI method. Visually impaired users were also evaluated in order to evaluate the use of the speaking function. This study was conducted at two universities and three university hospital centers, and using capillary blood samples collected from 100 lay users (50 were visually impaired, ranging from moderately to profoundly impaired as defined in the ICD-10 of the World Health Organization Classification). The glucose sample ranges were from 59.7 – 385 mg/dL (according to YSI). The results of this study, linearity, and method comparison support the claimed measuring range of 20 – 600 mg/dL. The regression analysis is as follows:

Regression analysis of professional and lay users

	Professional	Lay users
Slope(comparison with YSI)	0.9855	0.9711
Y-Intercept(comparison with YSI)	-1.7629	1.3322
R2(comparison with YSI)	0.9788	0.9782

Regression analysis of alternative sites

	Palm	Forearm	Upper arm	Calf	Thigh
Slope(comparison with YSI)	1.0199	1.0206	1.0052	0.9929	0.9904
Y-Intercept(comparison with YSI)	-2.4592	-2.426	-1.2449	-1.9149	-1.4631
R2(comparison with YSI)	0.966	0.9641	0.9719	0.9706	0.9743

SYSTEM ACCURACY RESULTS

System accuracy analysis of professional and lay users glucose concentrations < 75 mg/dL

	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
professional	10/17 (59%)	16/17 (94%)	17/17(100%)
lay users	9/17 (53%)	16/17 (94%)	17/17(100%)

System accuracy analysis of professional and lay users glucose concentrations ≥ 75 mg/dL

	Within ±5%	Within ±10%	Within ±15%	Within ±20%
professional	30/83(36%)	66/83(80%)	76/83(92%)	81/83(98%)
lay users	28/83(34%)	62/83(75%)	82/83(99%)	82/83(99%)

System accuracy analysis of lay users performing alternative site testing on glucose concentrations < 75 mg/dL

System accuracy analysis of alternative sites glucose concentrations < 75 mg/dL

Difference range in values between the alternative sites and YSI	within ±5mg/dL	within ±10mg/dL	within ±15mg/dL
Palm	9/17 (53%)	13/17 (76%)	17/17 (100%)
Forearm	8/17 (47%)	14/17 (82%)	17/17 (100%)
Upper arm	13/17 (76%)	16/17 (94%)	17/17 (100%)
Calf	10/17 (59%)	14/17 (82%)	17/17 (100%)
Thigh	10/17 (59%)	15/17 (88%)	17/17 (100%)

System accuracy analysis of lay users performing alternative site testing on glucose concentrations of glucose concentrations ≥75 mg/dL

Difference range in values between the alternative sites and YSI	within ±5%	within ±10%	within ±15%	within ±20%
Palm	27/83 (32%)	53/83 (64%)	76/83 (92%)	82/83 (99%)
Forearm	21/83 (25%)	58/83 (70%)	74/83 (89%)	81/83 (98%)
Upper arm	25/83 (30%)	64/83 (77%)	75/83 (90%)	82/83 (99%)
Calf	28/83 (34%)	59/83 (71%)	75/83 (90%)	81/83 (98%)
Thigh	32/83 (38%)	62/83 (75%)	81/83 (98%)	82/83 (99%)

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:

Time of day	People without diabetes
Fasting and before meals	<100 mg/dL
2 hours after meals	<140 mg/dL

(1) American Diabetes Association: Diagnosis and Classification of Diabetes Mellitus m(Position Statement). *Diabetes Care* 34 (Supp. 1) S66, 2011.

N. Instrument Name:

Clever Choice Voice+ S Blood Glucose Monitoring System

Clever Choice Voice+ M Blood Glucose Monitoring System

Clever Choice+ S Blood Glucose Monitoring System

Clever Choice+ M Blood Glucose Monitoring System

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and requires a sample volume of 0.7 μL.

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

   Yes ___X_____ 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 _____

3. Specimen Identification:

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

4. Specimen Sampling and Handling:

   The glucose test is intended to be used with capillary whole blood from the fingertip, palm, forearm, upper arm, calf, and thigh. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   There is no calibration required for the Clever Choice meters by the user. The meter is plasma-calibrated.

6. Quality Control:

   There are 3 levels of glucose control solutions available separately. Level 2 is provided with the start up kit. The meter has an algorithm to automatically recognize the control solutions to prevent control results from being stored in the

internal memory as a patient result. Recommendations on when to test the control materials are provided in the labeling. The control solution readings are not included in the average of the patient results. An acceptable range for each control level is printed on the control solutions vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

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

1. **Altitude Study :** To evaluate the effects of altitude on the Clever Choice meters, 20 whole blood venous samples were collected, using lithium heparin as the anticoagulant, and then split into 3 environmental simulation chambers (N=80, glucose range 72.3 - 342 mg/dL). One lot of test strips was used in the study and each whole blood part was evaluated on four meters and compared to the YSI 2300 reference method. The environmental chambers were set to recreate three different altitude levels: 3,280 feet (1000 meters), 6,560 feet (2000 meters), and 10,744 feet (3275 meters). Additionally, samples were evaluated at sea level. Results obtained were analyzed as a percent bias compared to YSI. Based on the data, the Clever Choice Voice+ S ,Clever Choice Voice+ M, Clever Choice+ S (non-voice version), and Clever Choice+ M (non-voice version) glucose meters can be used at altitudes up to 10,744 feet (3275 meters).

2. Hematocrit Study: The test strips and meter system for this submission are identical to those cleared in k101307. Please see k101307 for information regarding hematocrit effects on this test system.

3. Temperature and Relative Humidity Study: The sponsor performed temperature and humidity studies using venous blood samples at target glucose concentrations (70, 125, 310 mg/dL) to evaluate combined temperature and relative humidity conditions (12.0ºC/25% RH, 23 ºC/ 25% RH, 38 ºC/25% RH, 12 ºC/80% RH, 12 ºC/ 60%RH, 38 ºC/80%RH). The results demonstrate that accurate readings can obtained after exposure to temperatures ranging from 50 - 104ºF (10 - 40ºC) and relative humidity conditions ranging from 25% – 80%.

4. EMC Electromagnetic Compatibility and Electrical Safety verification testing: The sponsor provided the appropriate documentation certifying that electromagnetic testing (EMS) had been performed and the Clever Choice meters were found compliant (IEC 61326, IEC 61010).

5. Sample volume study: The sponsor performed a study to verify the test strip sample volume requirement for the Clever Choice meters using blood samples at seven glucose concentrations (44.5, 63.1, 117, 168, 249, 356 and 437 mg/dL). Five sample volumes were evaluated in this study (0.5, 0.6, 0.7, 1.0 and 2.0 µL). Results support the claimed sample volume of 0.7 µL.

6. **Infection control:** The device is intended for both single- and multiple-patient use. Disinfection efficacy studies were performed on the materials comprising the meter and lancing device by an outside commercial testing demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Cavi-Wipes with EPA registration #46781-8. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter and lancing device (only for use with the single-patient use systems) after 11,000 cleaning and disinfection cycles designed to simulate 5 years of single-patient device use and 3 years of multiple-patient device use.. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

7. **Readability:** The results from the SMOG formula readability assessment demonstrated that the user's manuals, test strip package insert, and control solution package insert are at an 7.98 to 8.0 grade reading level.

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.