

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

A. 510(k) Number:

k110571

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative, amperometric assay, glucose oxidase

E. Applicant:

Telcare Incorporated

F. Proprietary and Established Names:

Telcare Blood Glucose Monitoring System
Telcare Blood Glucose Test Strips
Telcare Glucose Control Solutions
Telsolve Data Management System – Home Use
Telsolve Data Management System – Professional Use

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1345, Glucose test system
21 CFR 862.1660, Quality control material
21 CFR 862.2100, Calculator/data processing module for clinical use

2. Classification:

Class II, Class I (Reserved), Class I

3. Product code:

NBW, System, Test, Blood Glucose, Over The Counter
CGA, Glucose Oxidase, Glucose

JJX, Quality Control Material
JQP, Calculator/Data Processing Module, For Clinical Use

4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
See Indications for Use below.
2. Indications(s) for use:

Telcare Blood Glucose Monitoring System

The Telcare 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. It is intended for lay use by persons with diabetes to aid in diabetes management. It is indicated for use at home (over the counter [OTC]) and should be used only by a single patient and should not be shared. Testing is done outside the body (*in vitro* diagnostic use). The Telcare Blood Glucose Monitoring System consists of the Telcare Blood Glucose Meter, Telcare Blood Glucose Test Strips, and Telcare Glucose Control Solutions. The Telcare Blood Glucose Monitoring system is not indicated for the diagnosis or screening of diabetes or for neonatal use. Palm and forearm testing should be done only during steady-state times when glucose is not changing rapidly. The Telcare Blood Glucose Meter uses cellular data transmission to send test results to Telcare's remote database, Telsolve, and to receive messages from Telsolve. The Telcare Blood Glucose Monitoring System is not intended to provide automated treatment guidance or decisions, nor is it to be used as a substitute for professional healthcare judgment.

Telcare Blood Glucose Test Strips

The Telcare Blood Glucose Test Strips are to be used with the Telcare Blood Glucose Meter for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, palm, or forearm. These test strips are intended for lay use by persons with diabetes and should only be used by a single patient. They are not indicated for the diagnosis or screening of diabetes or for neonatal use. Palm and forearm testing should be done only during steady-state times when glucose is not changing rapidly.

Telcare Glucose Control Solutions

The purpose of the control solution is to validate the performance of the Telcare Blood Glucose Monitoring System by using a test solution with a known amount 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.

Telsolve Data Management System – Home Use

The Telsolve Data Management System – Home Use (Telsolve – Home) is an accessory to blood glucose monitoring systems for the review and evaluation of blood glucose test results to aid in diabetes management. Telsolve collects data from blood glucose meters

such as the Telcare BGM. Telsolve – Home is not intended to provide automated treatment guidance or decisions, nor is it to be used as a substitute for professional healthcare judgment.

Telsolve Data Management System – Professional Use

The Telsolve Data Management System – Professional Use (Telsolve – Pro) is an accessory to blood glucose monitoring systems for the review and evaluation of blood glucose test results to aid in diabetes management. Telsolve collects data from blood glucose meters such as the Telcare BGM.

3. Special conditions for use statement(s):

Over the Counter

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, critically ill or in a hyperosmolar state

Allows testing on the fingertip, palm, or forearm.

Alternative site testing should only be used during steady-state blood glucose conditions when glucose is not changing rapidly

Alternative site testing (AST) should not be used to calibrate continuous glucose monitors (CGMs) nor for use in insulin dose calculations.

4. Special instrument requirements:

The Telcare Blood Glucose Meter

I. Device Description:

The Telcare Blood Glucose Monitoring System (Telcare BGM system) consists of a meter, test strips, and control solutions (Level 1 and Level 2). The Telcare Blood Glucose Meter (Telcare meter), when used with the Telcare Blood Glucose Test Strip (Telcare Test Strip), quantitatively measures glucose in capillary whole blood. The Telcare Glucose Control Solutions (Telcare control solutions) are used by patients to verify the performance of the Telcare test strips and Telcare meter. An embedded cellular module within the Telcare meter enables wireless communication between the meter and Telcare’s remote database, called Telsolve Data Management System (Telsolve).

Telsolve is an accessory to blood glucose meters to assist in the review and evaluation of blood glucose test results and related information to aid in diabetes management. Telsolve consists of two different levels of functionality:

Telsolve Data Management System – Home Use

Telsolve Data Management System – Professional Use

Telsolve data can be viewed by the patient and by other person(s) authorized by the patient on a personal computer, or other internet-capable devices, including some smartphones,

provided a validated internet browser is used. The professional use version generates and returns an informational feedback message documenting compliance with patient-targets for blood glucose levels and testing frequency, directly to the patient via a secure internet portal. The specific browsers that have been validated for use are indicated in the labeling.

J. Substantial Equivalence Information:

1. Predicate device name(s):
 AutoSure Voice II Blood Glucose Monitoring System
 MCT-Diabetes (Data Management Software)
 Contrex Plus Level 1 and Level 2 Control Solutions from Gluco Track Blood Glucose Monitoring System

2. Predicate 510(k) number(s):
 k102037, k073699, k062799

3. Comparison with predicate:

Item	Candidate Device Telcare Blood Glucose Monitoring System	Predicate (k102037) AutoSure II Voice Glucose Monitoring System
Indications for use	The Telcare 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. It is intended for lay use by persons with diabetes to aid in diabetes management. It is indicated for use at home (over the counter) and should be used only by a single patient. Testing is done outside the body (<i>in vitro</i> diagnostic use). The Telcare Blood Glucose Monitoring System is not indicated for the diagnosis or screening of diabetes or for neonatal use. Palm and forearm testing should be done only during steady-state times when glucose is not changing rapidly. The Telcare Blood Glucose Meter uses cellular data transmission to send test results to Telcare’s remote database, Telsolve, and to receive messages from Telsolve. The Telcare Blood Glucose Monitoring System is not intended to	Same

Item	Candidate Device Telcare Blood Glucose Monitoring System	Predicate (k102037) AutoSure II Voice Glucose Monitoring System
	provide automated treatment guidance or decisions, nor is it to be used as a substitute for professional healthcare judgment.	
Test Principle	Electrochemical biosensor with carbon electrodes that measures current produced by a chemical reaction	Same
Enzyme	Glucose oxidase	Same
Sample Type	Fresh capillary whole blood	Same
Sample Site	Fingertip, the palm, the forearm	Same
Memory feature	300 measurement results with blood and control tests	Same
Day average	7-, 14-, 30- day average glucose result	Same
Measuring time	6 sec	Same
Measurement range	20-600 mg/dL	Same
Sample Volume	0.8 μ L	1.0 μ L
Meter dimensions (mm)	100(L)x60(W)x15(H) mm	93(L)x58(W)x20.5(H) mm
Weight (g)	115 g	79 g
Test strip	Telcare Test Strip	AutoSure Test Strip
Autocoding	Yes	Yes
Speaking function	No	Yes

Item	Candidate Device Telcare Control Solutions	Predicate (k062799) Contrex Plus Level 1 and Level 2 from Gluco Track Blood Glucose Monitoring System
Indications for use	The purpose of the control solution is to validate the performance of the Telcare Blood Glucose Monitoring System by using a test solution with a	Same

Item	Candidate Device Telcare Control Solutions	Predicate (k062799) Contrex Plus Level 1 and Level 2 from Gluco Track Blood Glucose Monitoring System
	known amount 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.	
Analyte	D-glucose	Same
Number of Levels and Target Ranges	2 levels Level 1: 79-106 mg/dL Level 2: 163-200 mg/dL	Same Level 1: 87-131 mg/dL Level 2: 186-200 mg/dL
Stability	Unopened (Shelf): 16 months at 15-30°C Opened: 3 months at 15-30°C	Unopened (Shelf): 24 months at room temperature Opened: 18 months at room temperature

Item	Candidate Devices Telsolve Data Management System – Home Use Telsolve Data Management System – Professional Use	Predicate (k073699) MCT-Diabetes Data Management Software
Indications for use	The Telsolve Data Management System – Home Use (Telsolve – Home) and Professional Use (Telsolve – Pro) is an accessory to blood glucose monitoring systems for the review and evaluation of blood glucose test results to aid in diabetes management. Telsolve – Home is not intended to provide automated treatment guidance or decisions, nor is it to be used as a substitute for professional healthcare judgment.	Same
Data Upload Capability	Cellular wireless uploading to database; viewed by PC or other internet-capable device	Same
Data Source	Compile data from Telsolve glucose	Compile data

Item	Candidate Devices Telsolve Data Management System – Home Use Telsolve Data Management System – Professional Use	Predicate (k073699) MCT-Diabetes Data Management Software
	meter	from multiple different brands of glucose meters
Browser Requirements	Microsoft Internet Explorer 7.0 and 8.0 Mozilla FireFox 3.0 Apple Safari 5.0.4 and 5.0.5 Apple iOS 4.2.1 Google Android 2.2.1	Microsoft Internet Explorer 6.0 or later
PC Requirements	Internet capable; no processor or memory requirements	Personal computer with Pentium 4 or greater, 256 MB of RAM memory, 10 GB secondary storage
Software use	Single (individual) or multiple (individual and health professional)	Same
Use in Clinic	Patient list available	Same
Technical Support	Yes	Same
User's Manual	Available on Internet while using program	Same
Autodetect COM port	Not applicable; wireless data sent to server via TC/IP	Yes
Installation of program	Internet based portal	Installed from internet link

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.
- CLSI EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach
- EN 55011 ISM RF Equipment. Electromagnetic disturbance characteristics. Limits and methods of measurement (2007)
- IEC 60601-1-2: Medical electrical equipment Part 1-2. General requirements for safety – Collateral Standard: EMC Requirements and Tests (2001)

- 61000-3-2 EMC – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current ≤ 16 A per phase) (2005)
- 61000-3-3 EMC-Part 3-3: Limits-Limitation vs. fluccts/flicker public low-v support systems (equipment with rated current ≤ 16 A per phase) (2005)
- 61326-1 Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements (2005)
- 61326-2-6 Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – IVD medical equipment (2005)
- 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements (2010)
- 61010-2-101 Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for IVD medical equipment (2002)
- 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety, Amendment 2 (1995)

L. Test Principle:

The test is based on electrochemical biosensor technology and the principle of capillary action. The electrical current generated by the reaction of glucose with the reagent of the strip is measured by the meter and is displayed as the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Within-run and between-run precision studies were performed. For the within-run precision studies 10 replicates of each lot of test strips, for each of 5 spiked venous whole blood glucose levels and two control solution levels were analyzed using 10 meters, and 3 lots of test strips. Within-run studies were performed daily for 20 days. Results are summarized below.

Samples	Test Strip Lot 1		
	Mean	SD	% CV
Interval 1 40-60 mg/dL	49	1.42	--
Interval 2 100-140 mg/dL	114	1.75	1.5
Interval 3 180-250 mg/dL	198	6.80	3.4
Interval 4 300-380 mg/dL	356	6.17	1.7

Interval 5 400-500 mg/dL	426	9.75	2.3
Control Level 1 79-106 mg/dL	90	2	1.7
Control Level 2 163-200 mg/dL	184	4.06	2.2

Test Strip Lot 2			
Samples	Mean	SD	% CV
Interval 1 40-60 mg/dL	50	2.36	--
Interval 2 100-140 mg/dL	114	3.07	2.7
Interval 3 180-250 mg/dL	197	4.40	2.2
Interval 4 300-380 mg/dL	370	9.98	2.7
Interval 5 400-500 mg/dL	433	11.47	2.6
Control Level 1 79-106 mg/dL	93	3.21	3.5
Control Level 2 163-200 mg/dL	187	4.25	2.3

Test Strip Lot 3			
Samples	Mean	SD	% CV
Interval 1 40-60 mg/dL	47	0.92	--
Interval 2 100-140 mg/dL	113	3.05	2.7
Interval 3 180-250 mg/dL	202	7.12	3.5
Interval 4 300-380 mg/dL	341	13.10	3.8
Interval 5 400-500 mg/dL	418	10.98	2.6
Control Level 1 79-106 mg/dL	88	3.06	3.5
Control Level 2 163-200 mg/dL	182	5.72	3.1

A between-run precision study consisting of 10 replicates of each lot of test strips, for each of 5 spiked venous whole blood glucose levels and two control solution levels

were analyzed using 10 meters, and 3 lots of test strips. Between-run precision was calculated for 20 days. Results from Day 20 are summarized below.

Test Strip Lot 1			
Samples	Mean	SD	% CV
Interval 1 40-60 mg/dL	50	1.87	--
Interval 2 100-140 mg/dL	116	4.08	3.5
Interval 3 180-250 mg/dL	196	4.47	2.3
Interval 4 300-380 mg/dL	357	5.80	1.6
Interval 5 400-500 mg/dL	436	10.47	2.4
Control Level 1 79-106 mg/dL	92	2.02	2.2
Control Level 2 163-200 mg/dL	195	4.12	2.1

Test Strip Lot 2			
Samples	Mean	SD	% CV
Interval 1 40-60 mg/dL	54	2.49	--
Interval 2 100-140 mg/dL	122	5.25	4.3
Interval 3 180-250 mg/dL	203	6.27	3.1
Interval 4 300-380 mg/dL	372	8.98	2.4
Interval 5 400-500 mg/dL	449	10.21	2.3
Control Level 1 79-106 mg/dL	96	2.66	2.8
Control Level 2 163-200 mg/dL	200	5.01	2.5

Test Strip Lot 3			
Samples	Mean	SD	% CV
Interval 1 40-60 mg/dL	45	1.70	--
Interval 2 100-140 mg/dL	110	3.84	3.5

Interval 3 180-250 mg/dL	189	5.76	3.1
Interval 4 300-380 mg/dL	343	8.19	2.4
Interval 5 400-500 mg/dL	429	11.24	2.6
Control Level 1 79-106 mg/dL	86	3.55	4.1
Control Level 2 163-200 mg/dL	185	5.08	2.7

b. *Linearity/assay reportable range:*

Linearity was evaluated using 3 lots of test strips, 10 Telcare blood glucose meters, and 8 venous whole blood samples with glucose levels ranging from 20-600 mg/dL, obtained by spiking pooled venous blood with a glucose solution. Each glucose level was analyzed 40 times over 3 test strip lots. Linear regression analysis for each test strip lot compared to the YSI resulted in:

$$\text{Test Strip Lot 1: } Y = 1.0193x - 2.242, r^2 = 0.9988$$

$$\text{Test Strip Lot 2: } Y = 1.0149x - 1.5461, r^2 = 0.9989$$

$$\text{Test Strip Lot 3: } Y = 1.0464x - 1.5289, r^2 = 0.9990$$

The claimed range of measurement for this device is 20 to 600 mg/dL.

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

The device showed traceability to a laboratory analyzer, YSI 2300 in the method comparison studies in 2.a. below.

Two levels of control material (Level 1 and Level 2) are available for use with this system.

Control Solutions	Level 1	Level 2
Glucose (mg/dL)	79 - 106	163 - 200

The following standard was used to trace the D-glucose analyte of the control solutions, Glucose Standard Set NERL 1343. NERL 1343 is traceable to the NIST glucose standard. Both levels of control solutions are provided with the meter of this submission.

Shelf life was evaluated through accelerated studies at 40°C using 3 lots of each level of control solution. Open vial stability was evaluated through real-time studies at

30°C and 85% humidity. The accelerated results support a 16 month shelf life claim at 15-30°C and the real-time studies a 3 month open vial stability claim at 15-30°C. Real-time stability studies for shelf-life of the control solutions are ongoing.

c. Detection limit:

The reportable range is 20 to 600 mg/dL based on linearity/reportable range studies above (section M.1.b.). The low and high detection limits for the Telcare Blood Glucose System have been set at 20 and 600 mg/dL. Readings below or above these values will generate a “Lo” or “Hi” result, respectively.

d. Analytical specificity:

The sponsor tested substances for interference using 1 lot of test strips, 10 meters, and 3 concentrations of glucose (70-90 mg/dL, 110-130 mg/dL, and 300-330 mg/dL). Analyte levels were achieved by adjusting human venous blood levels. Samples were then spiked with the following interfering substances. Each sample was analyzed 10 times. The labeling states that elevated concentration of L-DOPA, ibuprofen, tolazamide, ascorbic acid, fructose, uric acid, cholesterol, bilirubin (unconjugated and conjugated), and triglyceride may affect glucose test results. The following table lists the concentrations of each substance at which no significant interference as defined by the sponsor as $\leq 10\%$ was detected:

Interfering Substance	Therapeutic/ Physiological Levels (mg/dL)	Test Levels (mg/dL)
Acetaminophen	1.0 – 3.0	10 and 20
L-DOPA	1.0	1.5 and 3.0
Tolbutamide	5.4 – 10.8	10 and 64
Dopamine	N/A	0.05 and 0.1
Ibuprofen	1.0 – 7.0	25, 40, and 50
Salicylic Acid	10 - 30	40 and 65
Methyl-Dopa	1.0 – 7.5	0.75 and 1.5
Tetracycline	0.2 – 0.5	0.5 and 1.5
Ephedrine	0.014	0.02 and 0.05
Mannitol	10.0	15 and 30
Mannose	1.2	2.0 and 4.0
Sorbitol	0.05	0.1 and 0.2
Tolazamide	23.0	23, 60, and 70
Ascorbic Acid	0.4 – 2.0	3.0, 5.0 and 6.0
Maltose	N/A	20 and 50
EDTA	N/A	1x and 5x
Lactose	N/A	10 and 25
Heparin	N/A	1x and 5x

Maltotriose	N/A	120 and 240
Maltotetraose	N/A	60 and 120
Xylitol	0.02	0.05 and 0.1
Xylose	N/A	10.0 and 25.0
Fructose	1.0 – 6.0	10, 15, and 20
Hemoglobin	100 - 200	100 and 200
Creatinine	0.6 – 1.3	2.0 and 5.0
Uric Acid	2.5 – 8.0	15 and 23.5
Cholesterol	114 – 201	200, 400, and 500
Bilirubin-unconjugated	0.3 – 1.2	10, 15, and 20
Bilirubin-conjugated	0.0 – 0.3	15, 25, and 30
Triglyceride	30 – 300	500, 2000, and 3000
Galactose	Less than 5.0	10 and 15

e. *Assay cut-off:*
Not Applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

Reference Method Comparison:

The sponsor performed a system accuracy evaluation comparing the Telcare meter to YSI. Healthcare professionals tested 145 capillary samples in 6 concentration categories (50-80, 81-120, 121-200, 201-300, 301-400, and >400 mg/dL) per strip, using 3 meters and 3 lots of test strips using the Telcare meter and the YSI (the reference method). Seven additional hydrolyzed samples were also tested to obtain concentrations < 50 mg/dL, for a total of 152 samples tested. Results are summarized below.

For glucose concentrations <75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
19/28 (68%)	27/28 (96%)	28/28 (100%)

For glucose concentrations ≥ 75 mg/dL

within ± 5 %	Within ± 10 %	within ± 15 %	within ± 20 %
75/124 (60%)	121/124 (98%)	124/124 (100%)	124/124 (100%)

Linear Regression Analysis:

Comparison	N	Slope and y-intercept	R ²
Telcare vs. YSI	152	Y = 0.988x - 0.39	0.994

Fingerstick and Alternate Site Testing Comparison Studies:

The sponsor performed a lay-user study where accuracy of the device was tested using 145 fingerstick samples obtained by the lay-user and 145 samples per each alternative site (the palm and forearm) obtained by the lay-user. Participants, who were able to read the User's Manual in English, were instructed to read the manual and perform testing on the finger and then the alternative sites. A technician collected capillary blood for measurements on YSI. Results were obtained for each of the alternative sites. Samples ranged from 51 – 496 mg/dL. Results are summarized below.

For glucose concentrations < 75 mg/dL

Sites	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Finger	10/21 (48%)	20/21 (95%)	20/21 (95%)
Palm	11/21 (52%)	19/21 (90%)	21/21 (100%)
Forearm	9/21 (43%)	17/21 (81%)	21/21 (100%)

For glucose concentrations ≥ 75 mg/dL

Sites	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20%
Finger	67/124 (54%)	109/124 (88%)	122/124 (98%)	124/124 (100%)
Palm	57/124 (46%)	97/124 (78%)	112/124 (90%)	119/124 (96%)
Forearm	66/124 (53%)	98/124 (79%)	110/124 (89%)	119/124 (96%)

Linear Regression Analysis:

Comparison	N	Slope and y-intercept	R ²
Finger vs. YSI	145	Y = 0.980x - 0.39	0.993
Palm vs. YSI	145	Y = 0.998x - 4.37	0.989
Forearm vs. YSI	145	Y = 0.985x - 1.93	0.989

b. Matrix comparison:

Not applicable. Capillary whole blood is the only indicated matrix.

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):*
Not Applicable.

4. Clinical cut-off:
Not Applicable.

5. Expected values/Reference range:

Time of day	Range, Non-diabetes
Before meals	Less than 100 mg/dL
After meals	Less than 140 mg/dL

The sponsor references: American Diabetes Association. Standards of Medical care in Diabetes – 2010. Diabetes Care. 2010;33:S11-S61.

N. Instrument Name:

The Telcare Blood Glucose Meter,

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 or No _____.

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

Yes X or No _____.

Telsolve Data Management Software provides a web-based user interface that is compatible with Microsoft Internet Explorer, Mozilla FireFox, Apple Safari, Apple iOS, and Google Android.

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 their devices were designed and developed under good software life-cycle processes.

3. Specimen Identificaiton:
Samples are applied directly to the test strip as they are collected. Samples are identified by time, date, and/or time of meal stamps after measurement.
4. Specimen Sampling and Handling:
The Telcare meter is intended to be used with capillary whole blood from the finger, palm, and forearm. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.
5. Calibration:
The meter is a non-coding meter, therefore no coding is required by the user.
6. Quality Control:
The sponsor recommends two levels of Telcare glucose control solution, Level 1 and Level 2 with this device. To perform a control test the user is instructed to press the up/down buttons on the side of the meter to access the control solution modes. The user presses down buttons (once for Level 1 and twice for Level 2) and presses enter to select the mode. An acceptable range for each control level is printed on the test strip vial label. If the control values fall outside these ranges, 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:

1. The device (Telcare meter) is intended for single-patient use. Disinfection studies were performed on the meter and lancet device by an outside commercial testing service to determine the disinfection efficacy of the meter and lancing device to the recommended cleaning and disinfection protocol, and its effectiveness in preventing the spread of bloodborne pathogens, particularly hepatitis B virus (HBV). Dispatch Hospital Cleaner Disinfectant Towels with Bleach disposable wipes (EPA Reg. No: 56392-8) were validated, demonstrating complete inactivation of live virus for use with the meter and lancing device. The sponsor also conducted robustness studies and demonstrated that there was no change in performance or in the external materials of the meter and lancing device after 1,825 cleaning and disinfection cycles to simulate 5 years of use by lay-users. Each robustness cycle consisted of one pre-clean wipe and one disinfecting wipe.
2. The effect of different hematocrit levels was evaluated with 3 lots of test strips using 10 test strips at each of 5 concentration ranges of glucose (30-50, 51-110, 111-150, 250-350, and 451-550 mg/dL). Analyte samples were prepared from venous blood samples at 5 hematocrit levels at approximately 30, 35, 43, 50, and 55%. In total 750 glucose measurements were made. Each of the glucose results were compared to the value obtained from the same plasma glucose concentration obtained by YSI. Bias were reviewed and found to be acceptable. The sponsor claims a hematocrit range of 30-55%.
3. The effect of altitude was evaluated at five whole blood samples with glucose concentrations ranging from 50 to 440 mg/dL were tested at sea level and 3,150 meters

(10,335 feet) above sea level. Each blood glucose concentration was measured 20 times. The bias was calculated relative to YSI at sea level and at 3,150 meters. The results demonstrate that the system meets the accuracy acceptance criteria for testing at altitudes up to 3,150 meters with biases within $\pm 10\%$ for all tested blood glucose concentrations.

4. The sponsor performed temperature and humidity studies at the combined extremes of 10.5°C/RH: 18%, 39.8°C/RH: 18%, 10.6°C/RH: 94%, and 39.8°C/RH: 94%, with venous blood samples (55-440 mg/dL) that demonstrated that their device can be used at temperatures of 10°C to 40°C and 20-90% relative humidity.
5. Usability studies were designed to test human factors such as ease of operation of the Telsolve Data Management Software and evaluation of the instructions for use for this device. The survey group included a near-even representation of 133 male and female patients with Type I and Type II diabetes, as well as a group of 12 healthcare professionals. All responses were kept confidential and participants remained anonymous throughout all surveys. Data were reported in aggregate and no identifying information was linked back to individual responses.

The human factors that were most applicable to the Telsolve Data Management Software are the user characteristics (individuals with vision problems must be able to understand the system) and the device-user interface ensuring ease of operation, readability of the result, and unambiguous messages to the user.

The usability studies evaluated the set-up process, including registering with Telsolve, uploading of blood glucose data, and the display of blood glucose data. These studies resulted in changes to the user interface to display glucose data in larger font type and to clearly label glucose readings (i.e. “most recent reading”).

The usability testing and results were factored appropriately into the Risk Analysis. As problems were identified, software changes were made and documented. The final version after usability was identified as Version 1.9.

6. Telcare Blood Glucose Meter validation testing was performed to ensure that the glucose readings displayed in the Telsolve Data Management System were identical to those of the corresponding Telcare meter. Additional tests were conducted by the sponsor to V&V that the readings in each of the Telcare meters tested were the same reading, date and time shown on the meter itself and V&V with the Telsolve software. The testing proved that the Telsolve software represents exactly the same readings from the meters tested and they are displayed accurately within the Telsolve application.

The software documentation submitted indicates that the Telsolve software application was and is under well developed software lifecycle processes.

7. The sponsor provided a readability study and obtained Flesch-Kincaid Grade Level Scores of 7.4 for the Telcare Meter User’s Manual, 7.3 for the Telsolve Home User’s

Manuals, 7.9 for the Telsolve Professional User's Manuals, 7.9 for the Telcare test strip insert, and 7.8 for the Control Solution Insert.

8. The sponsor stated that they conformed to the following guidelines and provided the appropriate documentation to demonstrate compliance:
- EN 55011 ISM RF Equipment. Electromagnetic disturbance characteristics. Limits and methods of measurement (2007)
 - IEC 60601-1-2: Medical electrical equipment Part 1-2. General requirements for safety – Collateral Standard: EMC Requirements and Tests (2001)
 - 61000-3-2 EMC – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current ≤ 16 A per phase) (2005)
 - 61000-3-3 EMC-Part 3-3: Limits-Limitation vs. flucTs/flicker public low-v support systems (equipment with rated current ≤ 16 A per phase) (2005)
 - 61326-1 Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements (2005)
 - 61326-2-6 Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – IVD medical equipment (2005)
 - 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements (2010)
 - 61010-2-101 Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for IVD medical equipment (2002)
 - 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety, Amendment 2 (1995)

Q. Proposed Labeling:

The labeling is sufficient and does not satisfy 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.