



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

I Background Information:

A 510(k) Number

K200788

B Applicant

Arkray, Inc.

C Proprietary and Established Names

Assure Titanium Blood Glucose Monitoring System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PZI	Class II	21 CFR 862.1345 - Glucose Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

This submission is a Dual 510(k) and CLIA Waiver by Application (Dual Submission) for a new device, tracked as k200788 and CW200005.

B Measurand:

Glucose in fresh capillary whole blood drawn from the fingertips

C Type of Test:

Quantitative amperometric assay (glucose oxidase)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Assure Titanium Blood Glucose Monitoring System consists of the Assure Titanium Blood Glucose meter and the Assure Titanium Blood Glucose test strips. The Assure Titanium Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The system is intended for in vitro diagnostic, point of care use in endocrinology clinics and nursing or skilled nursing facilities, for multiple patient use. This system should only be used with single-use, auto-disabling lancing devices for drawing finger stick capillary blood.

The system is not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia.

The system is not intended for use in acute care or hospital settings.

The system is not intended for neonatal use.

The system is for prescription use only.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

For point-of-care use only.

In vitro diagnostic use.

Not for Alternative Site Testing (AST).

Do not use the Assure Titanium Blood Glucose Monitoring System for screening or diagnosis of diabetes.

Not indicated for use in patients undergoing tight glycemic control.

Do not use the Assure Titanium Blood Glucose Monitoring System to test neonates. The Assure Titanium Blood Glucose Monitoring System has not been validated for neonatal use.

Do not use at altitudes higher than 10,000 ft (3048 m) above sea level.

Use only Assure Titanium Blood Glucose Test Strips for testing with the Assure Titanium Blood Glucose Meter.

Assure Titanium device should not be used in patients receiving intensive medical intervention/therapy because of the potential for pre-analytical collection error and specifically in patients with decreased peripheral blood flow, as it may not reflect the true physiological state when test results are generated using capillary whole blood samples. Examples include, but are not limited to, severe hypotension, shock, hyperosmolar-hyperglycemia (with or without ketosis) and severe dehydration.

D Special Instrument Requirements:

Assure Titanium Blood Glucose Meter

IV Device/System Characteristics:

A Device Description:

The Assure Titanium Blood Glucose Monitoring System consists of a battery-powered Assure Titanium Blood Glucose meter, disposable single-use Assure Titanium Blood Glucose Test Strips, Assure Control-Control Solutions (Level 1, 2 and Level 3), Quick Reference Guide and User Manual. Assure Titanium Blood Glucose Test Strips and Assure Control-Control Solutions are not included in the kit package and should be purchased separately. The candidate test strips were previously cleared in k170064 as part of the GLUCOCARD W Blood Glucose Monitoring System.

B Principle of Operation:

The Assure Titanium Blood Glucose Monitoring System measures the amount of glucose in capillary whole blood from the fingertip quantitatively, using amperometric technology. The test is based on the measurement of the electric current generated by the reaction of the capillary whole blood glucose with glucose oxidase (GOD) and a mediator on the test strip (hexaammineruthenium (III) chloride). The magnitude of the resultant current is proportional to the glucose concentration in the sample. The detected current signal is then calculated by the meter and glucose concentration reading is then displayed on the meter.

Instrument Description Information:

1. Instrument Name:

Assure Titanium Blood Glucose 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 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 detection of the calibration code is automatic.

5. Quality Control:

The Assure Control - Control Solutions are aqueous solutions available at three different glucose levels (Level 1: 40 mg/L \pm 11% glucose, Level 2: 130 mg/L \pm 11% glucose, and Level 3: 360 mg/dL \pm 11% glucose). Instructions on how to order control solutions, and when to perform a control solution test are included in the labeling. The acceptable range for each control level is printed on the test strip bottle or on the bottom of the test strip box. The meter automatically recognizes and flags the test result in the memory as a control solution test result. The user is cautioned not to use the meter and to contact the customer support if the control result falls outside the ranges printed on the test strip vial label.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Statstrip Glucose Hospital Meter System

B Predicate 510(k) Number(s):

k132121

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>k200788</u>	<u>k132121</u>
Device Trade Name	Assure Titanium Blood Glucose Monitoring System	Statstrip Glucose Hospital Meter System
General Device Characteristic Similarities		
Intended Use/Indications For Use	Quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The system is intended for in vitro diagnostic, point of care, multiple patient use in endocrinology clinics and nursing or skilled nursing facilities, as an aid to measure glucose in the blood.	Quantitative determination of glucose in capillary finger stick, venous whole blood, arterial whole blood, neonate arterial whole blood and neonate heel stick specimens. Also for the quantitative determination of glucose in venous whole blood, arterial whole blood, neonatal heel stick, and neonatal arterial whole blood throughout all hospital

Device & Predicate Device(s):	<u>k200788</u>	<u>k132121</u>
		and all professional healthcare settings.
Test Principle	Electro-chemical biosensor (Amperometric)	Same
Enzyme	Glucose oxidase	Same
Measuring Range	10-600 mg/dL	Same
Calibration	Automated coded calibration	Same
General Device Characteristic Differences		
Sample Type	Fresh capillary whole blood	Whole Blood: Capillary, Venous, Arterial, and Neonate arterial whole blood
Test Strip Ejector	Yes	No
Controls	2 levels of Assure Control Solutions	3 levels of Nova StatStrip Control Solutions
Sample Volume	0.5 µL	1.2 µL
Operating Conditions	46-104 °F (8-40 °C) / 10-90% RH	59-104 °F (15-40 °C) / 10-90% RH
Hematocrit Range	10-70 %	20-65 %
Measuring Time	7 seconds	6 seconds

VI Standards/Guidance Documents Referenced:

IEC 60601-1-2: 2014, Medical electrical equipment - Part 1-2: General requirements for safety - Collateral Standard: Electromagnetic compatibility - Requirements and tests.

CLSI EP06-A: 2003, Evaluation of the linearity of quantitative analytical Methods: A Statistical Approach.

CLSI EP07-A2: 2005, Interference Testing in Clinical Chemistry, Approved Guideline, 2nd Edition.

CLSI EP25-A: 2009, Evaluation of stability of *in vitro* diagnostic reagents.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Within-run and intermediate precision for the Assure Titanium Blood Glucose Monitoring System were evaluated to assess imprecision of the system across the glucose measuring range and under normal use conditions.

Within-run precision was evaluated using venous whole blood spiked with high concentration glucose solution or allowed to glycolyze to achieve 5 glucose concentrations (30-50, 51-110, 111-150, 151-250 and 250-400 mg/dL). Each level was tested with three lots of test strips in replicates of 10 on each of 10 meters for a total of 300 results per glucose concentration and 1500 results total. Results for the within-run precision testing are summarized in the table below.

Glucose Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	%CV
30-50	1	100	45.7	1.2	2.6%
	2	100	44.4	1.3	2.9%
	3	100	42.6	1.0	2.4%
	Combined	300	44.2	1.7	3.9%
51-110	1	100	96.3	2.0	2.1%
	2	100	95.7	2.0	2.1%
	3	100	92.8	2.3	2.4%
	Combined	300	94.9	2.6	2.7%
111-150	1	100	140.2	3.1	2.2%
	2	100	137.8	2.8	2.0%
	3	100	139.6	3.2	2.3%
	Combined	300	139.2	3.2	2.3%
151-250	1	100	203.7	6.2	3.1%
	2	100	202.7	3.8	1.9%
	3	100	204.9	4.9	2.4%
	Combined	300	203.8	5.1	2.5%
251-400	1	100	324.3	10.1	3.1%
	2	100	324.2	7.5	2.3%
	3	100	324.1	8.7	2.7%
	Combined	300	342.2	8.8	2.7%

Intermediate precision was evaluated using 5 control solutions at glucose levels within the ranges of 30-50, 51-100, 111-150, 151-250, and 251-400 mg/dL. Multiple operators tested the control solutions over 10 days using 3 lots of test strips and 10 meters, conducting one measurement per meter per day at the different glucose ranges. This resulted in 50 tests per lot per day for a total of 1500 tests. Results for intermediate precision testing are summarized in the table below.

Glucose Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	%CV
30-50	1	100	42.8	0.8	1.9
	2	100	42.4	0.7	1.6
	3	100	42.0	0.6	1.5
	Combined	300	42.4	0.8	1.9
51-110	1	100	87.3	1.4	1.6
	2	100	87.4	1.1	1.2
	3	100	86.2	1.4	1.7
	Combined	300	87.0	1.4	1.6
111-150	1	100	129.8	1.7	1.3
	2	100	129.7	1.4	1.1
	3	100	128.5	1.8	1.4
	Combined	300	129.3	1.8	1.4
151-250	1	100	256.6	3.2	1.3
	2	100	255.8	3.3	1.3
	3	100	251.8	3.5	1.4
	Combined	300	254.7	3.9	1.5
251-400	1	100	363.9	5.3	1.5
	2	100	364.6	5.6	1.5
	3	100	353.4	5.5	1.6
	Combined	300	360.6	7.5	2.1

2. Linearity:

Linearity of the Assure Titanium Blood Glucose Monitoring System was evaluated using venous whole blood spiked with high concentration glucose solution or allowed to glycolyze to achieve 11 glucose concentrations (6.3, 31.2, 46.9, 68.9, 135.0, 197.0, 254.5, 351.9, 421.0, 493.5 and 613.3 mg/dL). The target glucose concentrations were verified by the comparator method (YSI 2300 STAT Plus analyzer). Results on the candidate device were compared to results on the comparator. Each glucose level was tested using 3 test strip lots and 5 meters, for a total of 15 replicates per level and a total of 165 results.

Linear regression data analysis, with regression equation and coefficient of determination (R^2) presented for each lot tested is summarized in the table below:

Lot	Linear Regression Equation	R^2
1	$y = 1.0079x + 3.9485$	0.9988
2	$y = 1.0063x + 3.3727$	0.9993
3	$y = 0.9902x + 2.1839$	0.9999

The results of the study support linearity of the Assure Titanium Blood Glucose Monitoring System across the claimed measuring range of 10-600 mg/dL. If the concentration of a sample is less than 10 mg/dL glucose, the result is flagged by the meter as “Lo”. If a sample exceeds 600 mg/dL glucose, the result is flagged by the meter as “Hi”. The “Lo” and “Hi” functions were validated and demonstrated to function as intended.

3. Analytical Specificity/Interference:

Interference testing was conducted to evaluate the effect of common endogenous substances and exogenous substances expected in the intended use population on the Assure Titanium Blood Glucose Monitoring System. Additional potential interferents were included in the testing following a detailed analysis of medications and medical conditions of the subjects evaluated in the method comparison study (please see the tables in Section VII.B.1 below for a detailed list of medications and conditions). The study was designed using whole blood samples spiked or allowed to glycolyze to 3 target glucose levels (50-70 mg/dL, 110-130 mg/dL, and 225-270 mg/dL). Samples were divided into a test pool with the potential interferent added and a control sample with no added interferent. Each interferent was tested at clinically relevant concentrations.

Results on the candidate meter from the test samples were compared to results obtained on the candidate meter from the control sample. If interference was observed, additional testing was performed to determine the concentration at which the interference starts to occur. Potentially interfering substances, the maximum concentrations tested and the highest tested concentration at which no significant interference (defined by the sponsor as average % bias $\leq 10\%$) was observed are listed in the table below:

Potential Interfering Substance	Highest Concentration with no Significant Interference
Acetaminophen	20 mg/dL
Ascorbic acid	4 mg/dL
Conjugated Bilirubin	50 mg/dL
Unconjugated Bilirubin	40 mg/dL
Cholesterol	500 mg/dL
Creatinine	15 mg/dL
Dopamine	20 mg/dL
EDTA	180 mg/dL
Galactose	60 mg/dL

Potential Interfering Substance	Highest Concentration with no Significant Interference
Gentisic acid	700 mg/dL
Reduced Glutathione	92 mg/dL
Hemoglobin	20,000 mg/dL
Heparin	500 IU/dL
Ibuprofen	50 mg/dL
Icodextrin	1094.4 mg/dL
L-Dopa	0.75 mg/dL
Maltose	5,000 mg/dL
Methyl-L-dopa	1000 mg/dL
Salicylic acid	60 mg/dL
Sodium	414 mmol/L
Tolbutamide	100 mg/dL
Tolazamide	40 mg/dL
Triglycerides	1,500 mg/dL
Uric acid	24 mg/dL
Xylose	300 mg/dL
Xylitol	0.09 mg/dL
Mannitol	1,800 mg/dL
Fenofibric Acid	18 mg/dL
Canagliflozin	15 x 10 ⁻⁴ mg/dL
Amlodipine Besylate	18 x 10 ⁻⁴ mg/dL
Atorvastatin Calcium	84 x 10 ⁻⁴ mg/dL
Cilostazol	21 x 10 ⁻² mg/dL
Prasugrel	105 x 10 ⁻³ mg/dL
Nortriptyline HCl	45 x 10 ⁻⁶ mg/dL
Budesonide	36 x 10 ⁻⁵ mg/dL
Dextromethorphan	9 x 10 ⁻⁴ mg/dL
Oxcarbazepine	258 x 10 ⁻² mg/dL
Trihexyphenidyl HCL	15 x 10 ⁻³ mg/dL
Fluphenazine Decanoate	81 x 10 ⁻⁵ mg/dL
Levofloxacin	183 x 10 ⁻⁵ mg/dL
Glimiperide	576 x 10 ⁻⁴ mg/dL
Benazeprilat	297 nmol/dL
Saxagliptin	72 x 10 ⁻⁴ mg/dL
Morphine	28.3 nmol/dL
Ursodiol	7,836 x 10 ⁻⁴ mg/dL

Potential Interfering Substance	Highest Concentration with no Significant Interference
Silodosin	1848 x 10 ⁻⁵ mg/dL
Letrozole	31.2 nmol/dL

The following limitations are included in the user manual and test strip package insert:

- *Patients with high doses of Vitamin C intake (ascorbic acid; blood levels higher than 4 mg/dL) may yield inaccurate results.*
- *Patients undergoing oxygen therapy may yield inaccurate results.*

4. Assay Reportable Range:

The reportable range is 10 - 600 mg/dL.

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

The Assure Titanium Blood Glucose Monitoring System is traceable to the NIST (SRM) 917c glucose reference material. A method comparison was performed using the candidate device and YSI 2300 STAT Plus as the comparator method (see section VII.A.3 below).

Test Strip Stability

Shelf-life and open vial stability protocols and acceptance criteria for the Assure Titanium Blood Glucose Test Strips were previously evaluated in k170064 and were found to support the claimed shelf-life of 24 months and open vial stability of 6 months when stored at 34-86°F (1-30°C) and 10-90% relative humidity.

6. Detection Limit:

Not applicable.

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:

The performance of the Assure Titanium Blood Glucose Monitoring System was established in the intended use environment using capillary fingerstick samples from 396 patients at three clinical sites covering the two intended use settings (one nursing and skilled nursing facility and two endocrinology clinics) across the United States using untrained intended use operators (point-of-care operators). Site 1 was a 475-bed nursing and skilled nursing site. The study took place across both the long-term care nursing and rehabilitation unit (also known as a temporary care unit). Sites 2 and 3 were endocrinology clinics.

All testing with the Assure Titanium Blood Glucose Meter was performed by CLIA waived operators (non-laboratory personnel, e.g., registered nurses/licensed practical nurses, medical aides, office manager, receptionist).

The glucose levels tested ranged from 29.0 to 492.5 mg/L, with 32 results falling below 80 mg/dL and 22 results falling above 300 mg/dL. The hematocrit and sodium levels for all subjects tested were recorded. Testing was performed on six lots of Assure Titanium test strips using 26 Assure Titanium meters. The clinical study included subjects with reported 390 unique patient medical conditions receiving a total of 4066 unique medications, that accounted for 379 drugs classified by generic name, representing 14 main drug classes including nervous system, cardiovascular system, and alimentary tract and metabolism drug classes.

The Assure Titanium Blood Glucose Monitoring System results were compared to the YSI 2300 STAT Plus as the comparator method. The results were calculated separately for each type of clinical site as well as all sites combined.

Site	Site Type	Number of Patients	Glucose Range (mg/dL)	Hematocrit (%)
1	Nursing and skilled nursing facility	130	29.0-405.5	19-44
2	Endocrinology Clinic	165	43.7-492.5	25-51
3	Endocrinology Clinic	101	49.3-367.8	30-54

The results from the capillary fingerstick samples obtained from the Assure Titanium Blood Glucose Meter compared to the results from the comparator method, per site type, as well as all sites combined are summarized below:

Results for Glucose Concentrations <75 mg/dL:

Site	Within ±5 mg/dL	Within ±10 mg/dL	Within ±12 mg/dL	Within ±15 mg/dL
1	1/1 (100%)	1/1 (100%)	1/1 (100%)	1/1 (100%)
2 and 3	17/26 (65.4%)	25/26 (96.2%)	26/26 (100%)	26/26 (100%)
All sites combined	18/27 (66.7%)	26/27 (96.3%)	27/27 (100%)	27/27 (100%)

Results for Glucose Concentrations ≥75 mg/dL:

Site	Within ± 5%	Within ± 10%	Within ± 12%	Within ± 15%	Within ± 20%
1	80/129 (62.0 %)	122/129 (94.6%)	125/129 (96.9%)	128/129 (99.2%)	129/129 (100%)
2+3	163/240 (67.9%)	224/240 (93.3%)	230/240 (95.8%)	235/240 (97.9%)	240/240 (100%)
All sites combined	243/369 (65.9%)	346/369 (93.8%)	355/369 (96.2%)	363/369 (98.4%)	369/369 (100%)

The sponsor also conducted a usability study of the Assure Titanium Blood Glucose Monitoring System. The 10 point-of-care operators who participated in the study filled out two questionnaires: one concerning the ease of the use of the blood glucose system and one concerning the ease of understanding of the user manual and QRG. The results demonstrated that the participants were able to understand the labeling and conduct the testing on their own.

A readability assessment using SMOG analysis was conducted, and the results demonstrate that the of the user manual and quick reference guide (QRG) were written at a 7.4 and 7.2 grade level, respectively.

Patient Conditions:

The 396 study participants fell into the following medical condition categories that included over 415 unique patient medical conditions, as described in the table below:

Condition Category	Medical Condition	Number of Patients
Auditory	Excessive Cerumen	3
	Hard of Hearing	19
	Ruptured Eardrum	1
Biliary	Cholangitis	3
	Cholecystectomy	3
	Cholecystitis	1
	Cholelithiasis	2
Cancer	Benign Neoplasm	1
	Bone Cancer	1
	Brain Cancer	1

Condition Category	Medical Condition	Number of Patients
	Breast Cancer	8
	Breast Cancer, Historical	4
	Colon Cancer	1
	Colon Cancer, Historical	2
	Hepatocellular Carcinoma	1
	Leukemia	1
	Lipoma	2
	Liver Cancer	1
	Lung Cancer	2
	Lymphatic Cancer	1
	Meningioma	2
	Multiple Myeloma	1
	Non-Hodgkin's Lymphoma	1
	Pancreatic Cancer	1
	Prostate Cancer	6
	Renal Cancer	4
	Renal Cancer, Historical	1
	Skin Cancer	4
	Skin Cancer, Historical	3
	Throat Cancer	1
	Thyroid Cancer	2
	Thyroid Cancer, Historical	1
Cardiac	Aortic Aneurysm	3
	Aortic Insufficiency	1
	Aortic Regurgitation	1
	Aortic Stenosis	9
	Arrhythmia	2
	Arteriosclerosis	2
	Atrial Fibrillation	32
	Bradycardia	5
	Bundle Branch Block	3
	Cardiovascular Disease	3
	Carotid Artery Occlusion	1
	Chest Pain	1
	Chronic Systolic Heart Failure	1
	Coronary Artery Disease	36
	Elevated Troponin	2
	Endocarditis	2
	Heart Block	2
	Heart Disease	7
	Heart Failure	41
	Heart Murmur	3
Hypertension	248	
Hypotension	4	
Mitral Insufficiency	1	

Condition Category	Medical Condition	Number of Patients
	Mitral Regurgitation	2
	Mitral Stenosis	1
	Mitral Valve Prolapse	2
	Myocardial Infarction	3
	Myocarditis	1
	Occlusion and Stenosis of Carotid Artery	1
	Palpitations	2
	Patent Foramen Ovale	2
	Premature Atrial Contraction	1
	Premature Ventricular Contractions	1
	Sick Sinus Syndrome	1
	Sinus Node Dysfunction	1
	Sleep Apnea	19
	Tachycardia	4
	Tricuspid Regurgitation	1
	Ventricular Arrhythmia	1
	Ventricular Outflow Obstruction	1
	Dermatological	Abscess
Asteototic Dermatitis		1
Blepharitis		2
Dermatitis		7
Eczema		4
Erythema		1
Foot Complications		39
Intertrigo		3
Pruritic Disorder		1
Pruritus		5
Psoriasis		2
Rosacea		2
Seborrheic Dermatitis		3
Seborrheic Keratosis		4
Skin Complications		21
Skin Infection		3
Skin Ulcer		29
Tinea Pedis		3
Tinea Versicolor	1	
Endocrine	Adrenal Insufficiency	1
	Adrenal Nodule	1
	Gynecomastia	1
Gastro-Intestinal	Acid Reflux	1
	Celiac Disease	1
	Colitis	2
	Colon Polyp	2

Condition Category	Medical Condition	Number of Patients
	Constipation	68
	Diarrhea	15
	Diverticulitis	1
	Diverticulosis	1
	Gastroenteritis	1
	Gastroesophageal Reflux Disease	51
	Gastrointestinal Hemorrhage	2
	Gastrointestinal Problems	34
	Heartburn	1
	Incontinence	26
	Indigestion	2
	Irritable Bowel Syndrome	4
	Irritable Colon	1
	Ischemic Colitis	1
	Malabsorption Syndrome	1
	Nausea	6
	Pancreatitis	2
	Peptic Ulcer	3
	Rectal Prolapse	1
	Ulcer	1
Vomiting	5	
Hepatic	Bilirubinemia	1
	Cirrhosis	1
	Elevated INR	1
	Fatty Liver	2
	Hepatitis	1
	Hyperbilirubinemia	2
	Liver Dysfunction	8
	Subtherapeutic INR	2
	Supratherapeutic INR	1
	Transaminitis	1
Hypoalbuminemia	1	
Hormonal	Hyperprolactinemia	1
	Hypogonadism	3
	Polycystic Ovarian Syndrome	2
Immune	Arthritis	12
	Bacteremia	1
	Bacterial Infection	3
	Candida Infection	3
	Cellulitis	2
	Cold Sores	1
	Crohn's	1
	Eosinophilia	1
Fever	7	

Condition Category	Medical Condition	Number of Patients
	Gout	19
	Herpes Zoster	1
	Idiopathic Thrombocytopenic Purpura	1
	Immunodeficiency	1
	Immunosuppression	1
	Joint Inflammation	1
	Leukocytosis	16
	Leukopenia	1
	Lichen Planus	1
	Lymphadenitis	1
	Lymphedema	1
	Myasthenia Gravis	2
	Myelodysplastic Syndrome	1
	Oligoarthritis	1
	Onychomycosis	3
	Paronychia	1
	Photosensitivity	1
	Plantar Fasciitis	1
	Polymyalgia Rheumatica	2
	Rheumatoid Arthritis	10
	Sepsis	2
	Septic Arthritis	1
	Sjogrens Syndrome	1
	Verruca	1
Lipid Disorder	Dyslipidemia	11
	Hyperlipidemia	126
Metabolic	Diabetic Ketoacidosis	1
	Gestational Diabetes	1
	Hemochromatosis	1
	Hereditary Coproporphryia	1
	Hypercalcemia	4
	Hypercholesteremia	2
	Hypercholesterolemia	1
	Hyperglycemia	2
	Hyperkalemia	6
	Hypernatremia	3
	Hyperuricemia	1
	Hypocalcemia	1
	Hypoglycemia	5
	Hypokalemia	16
	Hypomagnesemia	6
	Hyponatremia	13
	Malnutrition	15
	Microalbuminuria	1
	Obesity	12

Condition Category	Medical Condition	Number of Patients
	Tumoral Calcinosis	1
	Vitamin Deficiency	42
	Weight Gain	5
	Weight Loss	19
Musculoskeletal	Achalasia	1
	Bursitis	3
	Cervical Spondylosis	3
	Contracture	1
	Degenerative Disc Disease	2
	Degenerative Spondylolisthesis	1
	Dysarthria	2
	Dystonia	1
	Esophageal Dysmotility	1
	Hernia	7
	Kyphosis	2
	Leg Cramp	1
	Monoclonal Gammopathy of Unknown Significance	2
	Muscle Spasms	2
	Muscle Weakness	8
	Muscular Dystrophy	1
	Myalgia	1
	Myositis	1
	Osteoarthritis	37
	Osteomyelitis	6
	Osteopenia	3
	Osteoporosis	24
	Pancytopenia	3
	Polyarthralgia	2
	Scoliosis	2
	Spinal Stenosis	16
	Temporomandibular Joint Syndrome	1
Tendinitis	2	
Neurological	Agitation	2
	Alzheimer's	14
	Amnesia	1
	Anorexia	4
	Anxiety	27
	Autonomic Neuropathy	1
	Bipolar Disorder	2
	Carpal Tunnel	3
	Cervical Radiculopathy	1
	Cervicalgia	1
	Chronic Hypomanic	1

Condition Category	Medical Condition	Number of Patients
	Chronic Pain	60
	Claustrophobia	1
	Cognitive Impairment	30
	Concussion	1
	Cord Compression	1
	Delirium	13
	Delusions	2
	Dementia	33
	Depression	45
	Diplegia	1
	Dizziness	6
	Dysautonomia	1
	Dysphagia	27
	Dysphonia	1
	Dysthymia	1
	Encephalopathy	12
	Essential Tremor	2
	Excoriation	1
	Fibromyalgia	2
	Globus Sensation	1
	Hallucinations	2
	Headache	1
	Lumbar Radiculopathy	2
	Memory Issues	2
	Migraine	2
	Mood Disorder	1
	Motor Skill Impairment	11
	Myoclonus	1
	Narcolepsy	1
	Neuralgia	2
	Neurologic Neglect Syndrome	1
	Neuropathy	98
	Nicotine Addiction	1
	Obsessive Compulsive Disorder	1
	Orthostatic Hypertension	1
	Orthostatic Hypotension	11
	Palsy	1
	Panic Attacks	1
	Parkinson's	7
	Polyneuropathy	4
	Post-Traumatic Stress Disorder	1
	Postural Orthostatic Tachycardia Syndrome	1

Condition Category	Medical Condition	Number of Patients
	Radicular Syndrome	1
	Schizophrenia	1
	Sciatica	2
	Seizures	4
	Somnolence	1
	Syrinx of Spinal Cord	1
	Tardive Dyskinesia	1
	Tremor	1
	Vascular Dementia	3
	Vasovagal Syncope	1
	Vertigo	4
Ocular	Blindness	10
	Bullous Keratopathy	1
	Cataract	15
	Conjunctivitis	4
	Dry Eye	7
	Glaucoma	22
	Macular Degeneration	6
	Macular Edema	1
	Pseudophakia	2
	Retinopathy	1
	Vision Problems	78
Oral	Visual Impairment	1
	Dental Abscess	1
	Gingival Bleeding	1
Other	Xerostomia	4
	Abnormal Gait	26
	Apathy	1
	Ascites	1
	Balance Issues	45
	Debility	55
	Dehydration	3
	Fatigue	3
	Frailty Syndrome	4
	Hyperproteinemia	1
	Hypothermia	1
	Impaired Mobility	1
	Insomnia	53
	Lethargy	4
	Mobility Issues	1
	Organ Prolapse	3
	Overweight	1
Polypharmacy	6	
Polytrauma	1	
Sequela	1	

Condition Category	Medical Condition	Number of Patients
Pancreatic	Intraductal Papillary Mucinous Neoplasm	1
Renal	Acute Kidney Disease	28
	Chronic Kidney Disease	54
	Diabetes Insipidus	1
	Elevated Alkaline Phosphatase	1
	Elevated Uric Acid	1
	Hematuria	7
	Hepatorenal Syndrome	1
	Hyperosmolality	1
	Interstitial Nephritis	1
	Kidney Disease	49
	Nephrolithiasis	1
	Nephropathy	1
	Renal Mass	1
	Tubulointerstitial Disease	1
Reproductive	Benign Prostatic Hyperplasia	17
	Endometriosis	1
	Enlarged Prostate	2
	Impotence	25
	Prostatitis	1
Respiratory	Allergic Rhinitis	6
	Asthma	12
	Bronchiectasis	2
	Bronchitis	1
	Chronic Obstructive Pulmonary Disease	10
	Cough	17
	Dyspnea	2
	Hypercarbia	2
	Lung Disease	1
	Pickwickian Syndrome	1
	Pleural Effusion	2
	Pneumonia	13
	Pneumonitis	1
	Pulmonary Edema	5
	Pulmonary Embolism	1
	Pulmonary Fibrosis	1
	Pulmonary Infection	1
	Pulmonary Mycobacterial Infection	1
	Pulmonary Nodules	2
	Respiratory Failure	9
Restrictive Lung Disease	1	
Shortness of Breath	1	

Condition Category	Medical Condition	Number of Patients
	Sinusitis	2
	Upper Respiratory Infection	1
Thyroid	Diaphoresis	1
	Goiter	6
	Hashimoto's	4
	Hyperparathyroidism	4
	Hyperthyroidism	5
	Hypoparathyroidism	1
	Hypothyroidism	60
	Thyroid Disorder	2
Urinary	Thyroid Nodule	5
	Bacteriuria	1
	Bladder Diverticulus	1
	Cystitis	1
	Dysuria	6
	Frequent Urination	3
	Overactive Bladder	6
	Urinary Retention	15
Vascular	Urinary Tract Infection	25
	Anemia	65
	Aneurysm	4
	Arterial Embolism	1
	Artery Stenosis	2
	Atherosclerosis	3
	Cerebral Artery Syndrome	1
	Cerebral Microvascular Disease	1
	Cerebral Vascular Accident	9
	Cerebrovascular Disease	3
	Coagulopathy	2
	Contusion	3
	Deep Vein Thrombosis	3
	Edema	33
	Epistaxis	1
	Gangrene	2
	Hematoma	4
	Hemorrhage	6
	Hemorrhoids	11
	Hypocapnia	1
	Hypoxemia	6
	Hypoxia	6
	Ischemia	1
Methemoglobinemia	1	
Peripheral Vascular Disease	17	
Pulmonary Vascular Congestion	1	

Condition Category	Medical Condition	Number of Patients
	Purpura	2
	Stroke	30
	Swelling	3
	Syncope	1
	Thalassemia	1
	Thrombocytopenia	14
	Thrombocytosis	4
	Thrombosis	1
	Transient Ischemic Attack	3
	Varicose Veins	1
	Venous Insufficiency	5
	Venous Ulcer	2

Medications:

During the study, participants received a total of 4066 unique medications, that accounted for 379 drugs classified by generic name, representing multiple drug classes, as described in the table below:

Therapeutic Drug Class 2	Therapeutic Drug Class 3	Number of Patients
Agents Acting on the Renin-Angiotensin System	ACE Inhibitors, Plain	107
	Angiotensin II Receptor Blockers (ARBs), Plain	62
Agents Acting on the Renin-Angiotensin System	Angiotensin II Receptor Blockers (ARBs), Combinations	11
All Other Therapeutic Products	All Other Therapeutic Products	13
Anabolic Agents for Systemic Use	Other Mineral Supplements	29
Analgesics	Opioids	66
	Other Analgesics and Antipyretics	132
Anesthetics	Anesthetics, General	1
	Anesthetics, Local	23
Antianemic Preparations	Iron Preparations	32
	Vitamin B12 and Folic Acid	42
Antibacterials for Systemic Use	Beta-Lactam Antibacterials, Penicillins	13
	Other Antibacterials	8
	Other Beta-Lactam Antibacterials	5
	Quinolone Antibacterials	7
	Sulfonamides	6
Antibiotics and Chemotherapeutics for Dermatological Use	Tetracyclines	1
	Antibiotics for Topical Use	2
	Chemotherapeutics for Topical Use	1

Therapeutic Drug Class 2	Therapeutic Drug Class 3	Number of Patients
Antidiarrheals, Intestinal Inflammatory/Anti-infective Agents	Antidiarrheal Microorganisms	10
	Antipropulsives	7
	Intestinal Adsorbents	1
	Intestinal Anti-inflammatory Agents	35
	Other Antidiarrheals	2
Antiemetics and Antinauseants	Antiemetics and Antinauseants	19
Antiepileptics	Antiepileptics	110
Antifungals for Dermatologic Use	Antifungals for Systemic Use	1
	Antifungals for Topical Use	23
Antigout Preparations	Antigout Preparations	21
Antihistamines for Systemic Use	Antihistamines for Systemic Use	24
Antihypertensives	Antiadrenergic Agents, Generally Acting	5
	Antiadrenergic Agents, Peripherally Acting	6
	Arteriolar Smooth Muscle, Agents Acting on	8
	Other Antihypertensives	1
Anti-inflammatory and Antirheumatic Products	Anti-inflammatory and Antirheumatic Products, Non-Steroids	34
Antimycotics for Systemic Use	Antimycotics for Systemic Use	5
Antiobesity Preparations, Excl. Diet Products	Antiobesity Preparations, Excl. Diet Products	3
Anti-Parkinson Drugs	Anticholinergic Agents	2
	Dopaminergic Agents	16
Antiprotozoals	Agents Against Amoebiasis and Other Protozoal Diseases	1
	Antimalarials	5
Antiseptics and Disinfectants	Antiseptics and Disinfectants	1
Antithrombotic Agents	Antithrombotic Agents	237
Antivirals for Systemic use	Direct Acting Antivirals	5
Beta Blocking Agents	Beta Blocking Agents	147
	Beta Blocking Agents and Thiazides	1
Bile and Liver Therapy	Bile Therapy	1
Blood Substitutes and Perfusion Solutions	Irrigating Solutions	4
Calcium Channel Blockers	Selective Calcium Channel Blockers with Direct Cardiac Effects	16
	Selective Calcium Channel Blockers with Mainly Vascular Effects	64
Calcium Homeostasis	Anti-Parathyroid Agents	1

Therapeutic Drug Class 2	Therapeutic Drug Class 3	Number of Patients
	Parathyroid Hormones and Analogues	1
Cardiac Therapy	Antiarrhythmics, Class I and III	10
	Cardiac Glycosides	6
	Cardiac Stimulants, Excl. Cardiac Glycosides	4
	Other Cardiac Preparations	5
	Vasodilators Used in Cardiac Diseases	11
Corticosteroids for Systemic use	Corticosteroids for Systemic use, Plain	4
Corticosteroids, Dermatological Preparations	Corticosteroids, Plain	10
Cough and Cold Preparations	Cough Suppressants, Excl. Combinations with Expectorants	16
	Expectorants, Excl. Combinations with Cough Suppressants	10
Digestives, Incl. Enzymes	Digestives, Incl. Enzymes	10
Diuretics	Aldosterone Antagonists and Other Potassium-Sparing Agents	20
	High-Ceiling Diuretics	53
	Low-Ceiling Diuretics, Excl. Thiazides	3
	Low-Ceiling Diuretics, Thiazides	45
Drugs for Acid Related Disorders	Antacids	1
	Drugs for Peptic Ulcer and Gastro-Oesophageal Reflux Disease (GORD)	133
Drugs for Constipation	Drugs for Constipation	307
Drugs for Functional Gastrointestinal Disorders	Belladonna and Derivatives, Plain	4
	Drugs for Functional Gastrointestinal Disorders	21
	Propulsives	7
Drugs for Obstructive Airway Diseases	Adrenergics, Inhalants	53
	Other Drugs for Obstructive Airway Diseases, Inhalants	54
	Other Systemic Drugs for Obstructive Airway Diseases	15
Drugs for Treatment of Bone Diseases	Drugs Affecting Bone Structure and Mineralization	12
Drugs Used in Diabetes	Blood Glucose Lowering Drugs, Excl. Insulins	359

Therapeutic Drug Class 2	Therapeutic Drug Class 3	Number of Patients
	Insulins and Analogues	347
Ectoparasiticides, Incl. Scabicides, Insecticides, and Repellents	Ectoparasiticides, Incl. Scabicides	1
Emollients and Protectives	Emollients and Protectives	1
Endocrine Therapy	Hormone Antagonists and Related Agents	3
	Hormones and Related Agents	5
Gynecological Antiinfectives and Antiseptics	Antiinfectives and Antiseptics, Excl. Combinations with Corticosteroids	4
Immunosuppressants	Immunosuppressants	12
Lipid Modifying Agents	Lipid Modifying Agents, Plain	263
Mineral Supplements	Calcium	20
	Other Mineral Supplements	29
	Potassium	24
Muscle Relaxants	Muscle Relaxants, Centrally Acting Agents	11
Nasal Preparations	Decongestants and Other Nasal Preparations for Topical Use	7
Ophthalmologicals	Antiglaucoma Preparations and Miotics	51
	Antiinfectives	3
	Antiinflammatory Agents	5
	Decongestants and Antiallergics	8
	Ocular Vascular Disorder Agents	1
	Other Ophthalmologicals	1
Other Alimentary Tract and Metabolism Products	Other Alimentary Tract and Metabolism Products	4
	Other Mineral Supplements	29
Other Dermatological Preparations	Other Dermatological Preparations	2
Other Drugs for Disorders of the Musculo-Skeletal System	Other Drugs for Disorders of the Musculo-Skeletal System	1
Other Nervous System Drugs	Drugs Used in Addictive Disorders	3
	Other Nervous System Drugs	1
	Parasympathomimetics	1
Pituitary and Hypothalamic Hormones and Analogues	Posterior Pituitary Lobe Hormones	1
Preparations for Treatment of Wounds and Ulcers	Cicatrizants	1
Psycholeptics	Antipsychotics	16
	Anxiolytics	48
	Hypnotics and Sedatives	58
Psychonaleptics	Anti-Dementia Drugs	12
	Antidepressants	147

Therapeutic Drug Class 2	Therapeutic Drug Class 3	Number of Patients
	Psycholeptics and Psychanaleptics in Combination	8
	Psychostimulants, Agents Used for ADHD and Nootropics	13
Sex Hormones and Modulators of the Genital System	Androgens	6
	Estrogens	13
	Hormonal Contraceptives for Systemic Use	8
	Other Sex Hormones and Modulators fo the Genital System	2
	Progestogens	3
	Progestogens and Estrogens in Combination	1
Stomatological Preparations	Stomatological Preparations	1
Throat Preparations	Throat Preparations	2
Thyroid Therapy	Antithyroid Preparations	6
	Thyroid Preparations	96
Tonics	Other Mineral Supplements	29
Topical Products for Joint and Muscular Pain	Topical Products for Joint and Muscular Pain	3
Urologicals	Drugs Used in Benign Prostatic Hypertrophy	40
	Urologicals	18
Vasoprotectives	Agents for Treatment of Hemorrhoids and Anal Fissures for Topical Use	23
	Capillary Stabilizing Agents	1
Vitamins	Ascorbic Acid (Vitamin C), Incl. Combinations	19
	Calcium	20
	Multivitamins, Combinations	44
	Other Plain Vitamin Preparations	6
	Vitamin A and D, Incl. Combinations of the Two	123
	Vitamin B1, Plain and in Combination with Vitamin B6 and B12	7
	Vitamin B-Complex, Incl. Combinations	1

Accuracy at extreme glucose values:

An additional study was conducted to further assess the performance of the Assure Titanium Blood Glucose Monitoring System at the extreme upper and lower ends of the claimed measuring range. The sponsor altered 100 capillary whole blood samples from healthy donors, by spiking or allowing samples to glycolyze, to obtain 50 samples with glucose concentrations below 80 mg/dL (22.3-72.8 mg/dL, as measured by the comparator method) and 50 samples with glucose concentrations above 300 mg/dL (303.5-577.3 mg/dL, as measured by the comparator method).

Samples were tested on the Assure Titanium Blood Glucose Meter by intended use operators, using test strips from 3 lots and compared with the results obtained on the comparator method (YSI 2300 STAT Plus). The results are summarized below:

Results for Glucose Concentrations < 80 mg/dL:

Within ±5 mg/dL	Within ±10 mg/dL	Within ±12 mg/dL	Within ±15 mg/dL
43/50 (86%)	49/50 (98%)	50/50 (100%)	50/50 (100%)

Results for Glucose Concentrations > 300 mg/dL:

Within ±5 %	Within ±10 %	Within ±12 %	Within ±15 %	Within ±20 %
32/50 (64%)	46/50 (92%)	50/50 (100%)	50/50 (100%)	50/50 (100%)

2. Matrix Comparison:

Not applicable.

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):

Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Expected values for non-diabetics

Expected blood glucose values for non-pregnant adults without diabetes¹

Fasting* <100 mg/dL

2 hours after meals <140 mg/dL

*Fasting is defined as no caloric intake for at least eight hours. Consult the patient's physician to determine the range that is appropriate for your patients.

1. American Diabetes Association. Standards of medical care in diabetes-2021. Diabetes Care. 2021; 44(1); p.S17.

F Other Supportive Instrument Performance Characteristics Data:

1. Hematocrit Study:

The effect of hematocrit on the performance of the Assure Titanium Blood Glucose Monitoring System was evaluated at 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45% 50%, 55%, 60%, 65% and 70% hematocrit levels, and at 5 glucose concentrations (30-50, 51-110, 111-150, 151-250 and 251-400 mg/dL). Each sample was tested in replicates of 10 using 10 meters and 3 lots of test strips, for a total of 30 replicates per sample. The values were compared with the glucose measurements obtained from the comparator method (YSI 2300 STAT Plus). The results of the study demonstrated adequate performance to support the claimed hematocrit range of 10-70%.

2. Altitude Study:

A simulated high-altitude study was conducted in a pressure chamber to simulate the effects of sea level (<500 ft) and high-altitude (10,000 ft) on the Assure Titanium Blood Glucose Monitoring System. Venous whole blood samples adjusted to 3 glucose concentrations (55-77, 114-144 and 316-356 mg/dL) were tested in replicates of 10, using 10 meters and 3 lot of test strips, for a total of 30 replicates per sample, per condition. Values measured by the candidate device were compared with the glucose measurements obtained from the comparator method (YSI 2300 STAT Plus). The results of the study support the claim that the Assure Titanium Blood Glucose Monitoring System can be operated at altitudes of up to 10,000 ft (3,048 meters).

3. System Operating Conditions:

To assess the performance of the Assure Titanium Blood Glucose Monitoring System when used under various operating temperature and humidity conditions, the system was tested at four different temperature and humidity conditions including low temperature/low humidity (8 °C/10% RH), low temperature/high humidity (8 °C/90% RH), high temperature/low humidity (40 °C/10% RH) and high temperature/high humidity (40 °C/90% RH). Each of 3 venous whole blood glucose levels (55-77, 114-144 and 316-356 mg/dL) were tested by 10 meters, using 3 lots of test strips, for a total of 10 replicates per sample, per condition. Values measured by the Assure Titanium Blood Glucose Monitoring System were compared to the comparator method (YSI 2300 STAT Plus). The study results support the labeled operating conditions claim of 8-40°C (46-104°F) and 10-90% RH.

4. Sample Volume Study:

The sponsor performed a study to support the claimed minimum sample volume of 0.5 µL for the Assure Titanium Blood Glucose Monitoring System. Venous whole blood samples with 3 glucose concentrations (50-65, 100-120 and 200-250 mg/dL) were tested at 6 sample volumes (0.1, 0.3, 0.5, 1.0 and 5.0 and 10.0 µL) using 3 lots of test strips. Values obtained were compared to the comparator method (YSI 2300 STAT Plus). Results support the claimed minimum sample volume of 0.5 µL for the system. The meter has an error message displayed if enough blood is not added to the test strip. This feature was validated and was shown to function as intended.

5. Flex Studies:

Intermittent sampling, sample perturbation, testing with used test strips and a variety of mechanical/durability testing (i.e., drop, vibration and compression testing) was completed by the sponsor. The testing performed demonstrated that the Assure Titanium Blood Glucose Monitoring System is robust to these expected use scenarios.

6. Cleaning and Disinfection Robustness Evaluation:

The device is intended for multiple-patient use. Disinfection efficacy studies were performed on the exterior meter materials by an outside commercial testing laboratory, demonstrating complete inactivation of Hepatitis B Virus (HBV) with the chosen disinfectant, Super Sani-Cloth Germicidal Disposable Wipe (EPA Registration Number 9480-4). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 10,950 cycles of cleaning and disinfection using the chosen disinfectant. The robustness studies were designed to simulate cleaning and disinfection over the 3-year multi-patient use life of the meter. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

7. Electromagnetic Compatibility and Electrical Safety:

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

8. Test Strip Lot Release Protocol:

The test strip lot release protocol and acceptance 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.