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

I Background Information:

A 510(k) Number

K210933

B Applicant

YSI Incorporated

C Proprietary and Established Names

YSI 2900C Biochemistry Analyzer

D Regulatory Information

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

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Glucose

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 YSI 2900C Biochemistry Analyzer is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of venous whole blood samples, fingerstick capillary whole blood samples, serum and plasma in the laboratory.

For in vitro diagnostic use.

Glucose measurements from the YSI 2900C Biochemistry Analyzer are used in the diagnosis and treatment of carbohydrate metabolism disorders, including diabetes mellitus and idiopathic hypoglycemia, and of pancreatic islet cell tumors. The YSI 2900C Biochemistry Analyzer is not intended for use in the screening or quantitative analysis on neonates. The YSI 2900C Biochemistry Analyzer is not intended for point of care (POC) use.

This test is for prescription use only.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only
Not for Point-of-Care Use

D Special Instrument Requirements:

YSI 2900C Biochemistry Analyzer

IV Device/System Characteristics:

A Device Description:

The YSI 2900C Biochemistry Analyzer, is a laboratory instrument for determining glucose concentrations in human venous whole blood (dipotassium (K2EDTA), tripotassium EDTA (K3EDTA), sodium fluoride/potassium oxalate, lithium heparin, and sodium heparin), venous K2EDTA plasma, fingerstick capillary K3EDTA whole blood, and serum samples. The YSI 2900C Biochemistry Analyzer is a semi-automated electronic device that incorporates fluidics for sampling, calibrating, and flushing, contains a membrane-immobilized enzyme-coupled electrochemical detection system, and has a graphical user interface for control of the instrument and access to data.

The instrument contains two stations, one to accommodate plates or racks for batch sampling and a second for manual sampling from tubes or syringes.

Assay components are provided to the customer individually and are listed below.

Materials Required:

- YSI 2357 Buffer Concentrate Kit
- YSI 2747 D-Glucose Calibrator Standard
- YSI 1531 D-Glucose Linearity Standard
- YSI 2363 Potassium Ferrocyanide
- YSI 2365 Glucose (Dextrose) Membrane Kit
- YSI 2392 NaCl Solution

B Principle of Operation:

Glucose measurement is based on the level of H_2O_2 produced during the enzymatic reaction between glucose and oxygen molecules in the presence of the glucose oxidase enzyme. At a constant potential, electroactive H_2O_2 is oxidized at the surface of the platinum anode. The current generated by the flow of electrons at the surface of the platinum electrode is proportional to the glucose concentration of the sample.

C Instrument Description Information:

1. Instrument Name:

   YSI 2900C Biochemistry Analyzer

2. Specimen Identification:

   Specimen may be identified by scanning a barcode or by manually entering the information via the instrument touchscreen.

3. Specimen Sampling and Handling:

   A sample, contained in vials or tubes of various forms, is placed in a configured holder on the instrument. A robotic sampling sipper/injector travels to the sample and withdraws a sample from it. The glucose containing sample is transferred to and injected into a reaction chamber. Within the reaction chamber the sample is mixed to homogeneity with the co-contained system buffer.

4. Calibration:

   The YSI 2900C Biochemistry Analyzer's default setting is automatic self-calibration of the enzyme sensors every five samples or every fifteen minutes to a known concentration.

5. Quality Control:

   To ensure that the YSI 2900C Biochemistry Analyzer is operating properly, two levels of quality control should be used and daily operational checks should be performed before running samples as described in the operation manual.

V Substantial Equivalence Information:

A Predicate Device Name(s):
YSI MODEL 2300 STAT PLUS

B Predicate 510(k) Number(s):
K913806

C Comparison with Predicate(s):

Device & Predicate Device(s):	K210933	K913806
Device Trade Name	YSI 2900C Biochemistry Analyzer	YSI MODEL 2300 STAT PLUS
General Device Characteristic Similarities		
Intended Use/Indications For Use	Measurement of glucose in human whole blood, plasma and serum.	Same
Methodology	Amperometric	Same
General Device Characteristic Differences		
Sipper Pump	High-Precision stepper motor driving precision screw piston with check valve.	Stepper motor driving precision screw piston w/ check valve.

VI Standards/Guidance Documents Referenced:

Standards Organization	Standards Designation Number and Date	Title
IEC	61010-1 Edition 3. 2017-01	Safety requirements for electrical equipment for measurement control and laboratory use – Part 1: General Requirements
CLSI	CLSI AUTO 11-A2	Information Technology Security of In Vitro Diagnostic Instruments and Software Systems
IEC	60601-1-2 Edition 4.0 2014-02	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
ISO	14971 Third Edition 2019-12	Medical Devices – Application of Risk Management to Medical Devices
CLSI	EP05-A3 Third Edition	Evaluation of Precision of Quantitative Measurement Procedure

Standards Organization	Standards Designation Number and Date	Title
CLSI	EP06 Second Edition	Evaluation of Linearity of Quantitative Measurement Procedures
CLSI	EP07 Third Edition	Interference Testing in Clinical Chemistry
CLSI	EP09c Third Edition	Measurement Procedure Comparison and Bias Estimation Using Patient Samples
CLSI	EP37 First Edition	Supplemental Tables for Interference Testing in Clinical Chemistry
CLSI	EP17-A2 Second Edition	Evaluation of Detection Capability or Clinical Laboratory Measurement Procedures
CLSI	EP35 First Edition	Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   A precision study was conducted following the recommendations in the CLSI EP05- A3 guideline, third edition. Glucose levels at approximately 10, 50, 180, 400, 550, 700 and 900 mg/dL in sample pools were measured in duplicate per run with two runs per day for 20 days resulting in a total of 80 measurements per level.

   Representative precision at glucose levels approximately 10-900 mg/Dl:

Sample Type	Mean (mg/dL)	Repeatability		Within-Lab	
		SD	%CV	SD	%CV
Whole Blood	8.81	1.14	12.9	1.49	16.88
Whole Blood	50.24	0.88	1.7	1.12	2.23
Whole Blood	184.77	2.04	1.11	2.85	1.54
Whole Blood	400.94	5.02	1.3	6.68	1.67
Whole Blood	536.65	5.47	1.0	8.77	1.63
Whole Blood	724.71	9.54	1.3	12.71	1.75
Whole Blood	851.68	12.62	1.5	15.80	1.86
Plasma	16.45	1.03	6.2	1.10	6.67
Plasma	58.70	0.69	1.2	1.36	2.32
Plasma	187.66	2.52	1.3	3.26	1.74
Plasma	404.29	2.52	0.6	6.59	1.63
Plasma	542.66	3.49	0.6	10.21	1.88
Plasma	676.03	5.32	0.8	10.75	1.59
Plasma	855.13	5.13	0.6	11.15	1.30

2. Linearity:

Linearity testing was performed in accordance with CLSI EP06 2nd Edition. The dilution series contained whole blood and plasma samples spanning concentrations throughout the measuring range (1.9 to 998 mg/dL). The maximum % deviation from linearity observed within the claimed measuring range was less than 10%. The results of the linearity study support the claimed measuring range of 5-900 mg/dL.

3. Analytical Specificity/Interference:

The analytical specificity of the candidate device was established following the recommendations in CLSI EP07 guideline, third edition. Interference from certain exogenous and endogenous substances was assessed using venous whole blood samples at two glucose concentrations: low (40 mg/dL) and high (200 mg/dL). Control samples without interferent were included with each target glucose level. Five replicate measurements were obtained for each glucose level and control using three analyzers and three glucose membrane lots. The following table lists the target glucose and substance concentrations at which no significant interference was found.

Substance	Highest Concentration (mg/dL) that Does Not Cause Interference
Acetaminophen	20
Ascorbic Acid	6
Maltose	480
Xylose	50
Sorbitol	0.09
Heparin Sodium	500 IU/dL
Creatinine	15
Hemoglobin	1000
Tolbutamide	72
Galactose	60
Ibuprofen	50
EDTA	0.1
Triglycerides	1500
Sodium	1050
Gentisic Acid	1.8
Salicylic Acid	60
Dopamine	0.09
Maltitol	0.09
L-Methyldopa	2
Mannitol	1800
L-Dopa	1500
Isomalt	0.09
Lactitol	0.09
Xylitol	0.09
Tolazamide	9
Uric Acid	23.5
Conjugated Bilirubin	50
Unconjugated Bilirubin	40
Glutathione, Reduced	500
Cholesterol	500

D-xylose at concentrations higher than 100 mg/dL have significant interference and a warning was included in the sponsor's labeling as follows:

> **"**Patients undergoing a D-Xylose Absorption Test and their treating clinicians should be aware that concurrent testing for D-Glucose in the YSI 2900C Biochemical Analyzer may show a falsely elevated D-Glucose reading. D-Xylose is a substrate for the glucose oxidase enzyme in the sensing membrane and causes a positive interference. For example, at a Glucose concentration of 60mg/dL and Xylose concentration of 600mg/dL will produce a +12% bias.

Hyperglycemia may be incorrectly indicated and treatments based on those false results may be harmful to the patient.

Hypoglycemia may be incorrectly nonindicated and treatments based on those false results may be harmful to the patient.

Any D-Glucose results from the YSI instrument should not be used until the administered D-Xylose is known to be cleared from the patient."

Hematocrit at concentrations higher than 60% and lower than 20% may cause interference as described in the sponsor's labeling as follows:

"Hematocrit causes some varying proportional bias in the results. Elevated bias, up to 10%, may occur at hematocrit levels at 20 or below. Depressed bias, up to 10%, may occur at hematocrit levels at 60 and higher."

4. Assay Reportable Range:

Glucose measuring range = 5.0 – 900 mg/dL

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

The candidate device's standards are traceable to U.S. National Institute of Standards and Technology (NIST) glucose standard reference material SRM 917c.

6. Detection Limit:

Detection capability studies of blank (LoB), limit of detection (LoD) and limit of quantitation (LoQ) for glucose on the YSI 2900C Biochemistry Analyzer were conducted following the recommendations in CLSI EP17-A2 using whole blood and plasma samples. The results from all studies are summarized in the table below.

LOB, LOD and LOQ Results

Sample	LOB (mg/dL)	LOD (mg/dL)	LOQ (mg/dL)
Whole blood	0.24	1.69	4.00
Plasma	0.48	1.91	3.50

7. Assay Cut-Off:

Not Applicable.

8. Accuracy (Instrument):

Refer to section B.1. Method Comparison Studies.

9. Carry-Over:

The sponsor provided adequate information to support their device is not subject to carryover.

B Comparison Studies:

1. Method Comparison with Predicate Device:

A method comparison study was conducted following CLSI EP09c 3rd Edition. Three instruments/membrane lots were used for the candidate device and three analyzers for the comparator (i.e., the predicate). Testing was conducted at one site on serum, K2EDTA venous whole blood, K2EDTA venous plasma, and K3EDTA fingerstick whole blood capillary samples. Less than 10% of samples tested were contrived.

Weighted Deming regression results are presented below:

Sample Type	n	Range Tested (mg/dL)	Slope (95% CI)	Intercept (95%CI)	Pearson's r
Whole Blood samples	111	8.8-896	0.984 (0.975–0.944)	0.415 (-0.427 – 1.258)	0.99962
Plasma samples	101	8.54-940	0.982 (0.973–0.992)	0.069 (-0.887 – 1.026)	0.99976
Serum samples	101	9.82-910	0.988 (0.985–0.992)	-0.231 (-0.531 – 0.070)	0.99975
Capillary samples	111	63.7-389	1.004 (0.979-1.029)	-2.034 (-4.525-0.457)	0.99466

2. Matrix Comparison:

The sponsor has provided information to support that the glucose evaluated on the YSI 2900C Biochemistry Analyzer can be performed using K2EDTA, K3EDTA, lithium heparin, sodium heparin, and sodium fluoride/potassium oxalate on venous whole blood. K3EDTA is the only anticoagulant that should be used for capillary fingerstick whole blood and K2EDTA is the only anticoagulant that should be used for venous plasma samples.

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:

Normal (non-diabetic) adult fasting plasma glucose: Less than 100 mg/dL (5.55 mmol/L) and less than 140 mg/dL (7.77 mmol/L) 1-2 hours after meals.

Reference: ElSayed NA, Aleppo G, Aroda VR,et al, American Diabetes Association. 2. Classification and diagnosis of diabetes: Standards of Care in Diabetes-2023. Diabetes Care 2023; 46(Suppl. 1):S19-S40

F Other Supportive Instrument Performance Characteristics Data:

Not Applicable.

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.