September 30, 2024

YSI Incorporated
Eric Lute
Director QA
1725 Brannum Lane
Yellow Springs, Ohio 45387

Re: K210933
Trade/Device Name: YSI 2900C Biochemistry Analyzer
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CGA
Dated: May 5, 2023
Received: May 15, 2023

Dear Eric Lute:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Deputy Director
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K210933

Device Name

YSI 2900C Biochemistry Analyzer

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submitted by:

YSI Incorporated
1725 Brannum Lane
Yellow Springs, OH 45387 USA

510(k) Owner: YSI Incorporated
FDA Registration #: 1550101
510(k) # - K210933

Contact Person

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Director, QA
Ph: (937) 749-0587
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Date Prepared: 26-Sep-2024

Device Name: YSI 2900C Biochemistry Analyzer

Common Name: Glucose Analyzer

Classification Name: Glucose Test System (21 CFR 862.1345, Product Code CGA)

Predicate Device/Claims of Equivalence against YSI marketed MODEL 23A GLUCOSE ANALYZER; YSI 2300 STAT PLUS (referenced throughout as 2300 STAT PLUS). Reference 510(k): K913806.

There have been no prior applications or submissions for the review/approval of the YSI 2900C BIOCHEMISTRY ANALYZER.

Description of Device

The device under review, the 2900C Biochemistry Analyzer, is a laboratory instrument and *In Vitro Diagnostic Device* for determining glucose in human whole blood, plasma and serum taken from venous or capillary samples. The 2900C Biochemistry Analyzer is a semi-automated electronic device that incorporates fluidics for sampling, calibrating, and flushing, a membrane-immobilized enzyme-coupled electrochemical detection system with digital electronic control and has graphical user and data interfacing. It is designed for ambient indoor use in a technical laboratory environment.

The system is not intended to be a point of care product and is intended only for professional laboratory use.

The intended use and methods are shown to be substantially equivalent to the process and chemistry for glucose analysis as used in the 2300 STAT PLUS instrument (K913806). Lactate is not included in this submission as the feature has been disabled in the YSI 2900C Biochemistry Analyzer version of the system. There is no effect on glucose analysis in the system as the removal of lactate as the two assays are mutually exclusive.

Indications for Use of the YSI 2900C Biochemistry Analyzer

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.

Summary of Instrument Operation

Underlying Technology of YSI Biochemistry Analyzers - Operation

A blood or plasma 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 precisely withdraws a sample from it. The glucose containing sample is transferred to and precisely injected into a reaction chamber. Within the reaction chamber the sample is mixed to homogeneity with the co-contained system buffer within the precise volume of the chamber. The reaction chamber fluid is in direct contact with three electrodes – two sense electrodes and an auxiliary electrode. The technology of the device is described as an electrochemical detection system or more explicitly as coulometry or potentiostatic amperometry. The glucose in the reaction chamber fluid diffuses into an enzyme-containing membrane that overlays a platinum button electrode. Within the membrane the immobilized enzyme glucose oxidase catalytically reacts the glucose with dissolved oxygen. A product of this reaction, hydrogen peroxide, then diffuses to the platinum electrode. The platinum sense electrode, potentiostatically held at +0.7 volts, re-oxidizes the peroxide back into oxygen. This reoxidation creates an electric current which is detected and quantitated by the electronics in the instrument. The current detected is exactly proportional to the amount of glucose in the sample. The current created by the sample is compared to the current created by a calibrator solution of known exact glucose concentration and the glucose in the sample is computed by direct proportionality.

Principle of Measurement:

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 of 0.70 volts, 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.

Performance Testing Included with this Submission

The analytical performance of the YSI 2900C Biochemistry Analyzer is tested across the entire range of the instrument from 0.0 mg/dL to 900 mg/dL of glucose in whole blood and plasma. This span includes all four generally recognized medical decision points: 54, 70, 125, and 250 mg/dL, and includes other range intermediates and extrema. The data gained is used for Linearity Evaluation and comparison with the predicate device. A mirror of this testing was also performed concurrently on the predicate device, the YSI 2300 STAT PLUS Biochemistry Analyzer, for demonstration of substantial equivalence.

Nonclinical Tests

Testing to confirm instrument performance and establish system limits included:

- Limit of Blank
- Limit of Detection
- Limit of Quantification
- Environmental Conditions (Temperature and Humidity)
- Temperature Compensation Algorithm

Analytical and Clinical Validation

Testing was completed to show that the YSI 2900C Biochemistry Analyzer demonstrates substantial equivalence to the YSI 2300 StatPlus Analyzer. The performance testing included:

- Method Comparison Studies
- Precision/Reproducibility Studies
- Linearity Testing
- Specificity / Interference Testing
- Anticoagulant Matrix Equivalencies/Suitabilities
- Hematocrit Bias
- Stat Interrupt Biases
    - Stat Position Sampling
    - Syringe Position Sampling

The results of the performance testing confirmed that the YSI 2900C Biochemistry Analyzer demonstrates substantial equivalence to the YSI 2300 StatPlus Analyzer.

Table 1. Predicate comparison table to outline differences and similarities between the sample and predicate devices.

Description	Candidate Device 2900C BIOCHEMSITRY ANALYZER	Predicate Device 2300 STAT PLUS
Indications for Use	The 2900C Biochemistry Analyzer is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of venous, or capillary whole blood, serum and plasma in the laboratory. Glucose measurements from the 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 2900C Biochemistry Analyzer is not intended for use in the screening or quantitative analysis on neonates. The system is intended for prescription use only.	Determine glucose and lactate level in human whole blood or plasma
Size	Desktop	Same
Battery or mains powered	Mains powered	Same
Sample Volume	25 µL	Same
Method of Analysis	Enzyme mediated electrochemical detection	Same
Sample Introduction	Automated robotic sampler arm	Same
Installed Membrane Life	21 days	Same
Reagent/Test Tracking	Printed Data / Internal Database	Printed Data
Precision	2% or 2.0 mg/dL whichever is greater	±2% of the reading or 2.5 mg/dL (25 mg/L, 0.2 mmol/L), whichever is larger
QC Material	YSI product 1531 Glucose standard, 9.00 g/mL	Same
Calibration	Automatic, interval determined by user, recommended maximum is after 5 samples or 15 minutes since previous calibration	Same
User Interface	Touchscreen GUI	membrane switch panel and 2 line low resolution monochrome alphanumeric display

OS Software	Windows Embedded Standard 7 in Kiosk (read only) mode	None
Working Range	15–35°C, 10–75% humidity (non-condensing)	Same
Non-Interfering Anticoagulants	heparin sodium, dipotassium EDTA, sodium fluoride/potassium oxalate, tripotassium EDTA, Lithium Heparin	Same
Interferents	Listed in user manual	Same