October 18, 2022

Nova Biomedical Corporation
Robert Zinck
Senior Manager Regulatory Affairs
200 Prospect Street
Waltham, MA 02454

Re: K203549
Trade/Device Name: Nova Primary Glucose Analyzer System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: CGA
Dated: July 29, 2022
Received: August 2, 2022

Dear Robert Zinck:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 Caposino, Ph.D.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203549

Device Name
Nova Primary Glucose Analyzer System

Indications for Use *(Describe)*
The Nova Primary Glucose Analyzer System is indicated for in vitro diagnostic use by healthcare professionals in clinical laboratory setting for the quantitative determination of Glucose in lithium heparinized venous whole blood and plasma.

The measurement of Glucose is used in the diagnosis and treatment of carbohydrate metabolism disturbances including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and pancreatic islet cell carcinoma.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K203549

510(K) Owner: Nova Biomedical Corporation
Registration Number: 1219029
Address: 200 Prospect St.
Waltham, MA 02454
Phone: 781-894-0800
Fax Number: 784-891-4806
Contact Person: Robert Zinck, Senior Manager Regulatory Affairs

Date Prepared: October 14, 2022

Proprietary Name: Nova Primary Glucose Analyzer System

Common or Usual Name: Blood Glucose Analyzer

Classification Name:

Regulation section	Classification	Product code
21 CFR § 864.1345 Glucose Test System	Class II	CGA

Product Code:
CGA

Predicate Device:
k891480 –YSI 2300 Stat Glucose and L-Lactate Analyzer

Device Description:
The Nova Primary Glucose Analyzer System is a small, portable laboratory glucose analyzer that measures blood glucose levels in lithium heparinized whole blood or plasma utilizing a glucose oxidase based sensor and membrane/cap assembly.

The Nova Primary Glucose Analyzer accepts samples from syringes, blood collection tubes, microcentrifuge tubes, and sample cups. The sample size for analysis is 25 microliters (aspirated volume).

Nova Primary System Components:
The Nova Primary Glucose Analyzer System is comprised of the following components.

- Nova Primary Glucose Analyzer
- Nova Primary Glucose Sensor
- Nova Primary Glucose Membrane
- Nova Primary Calibrator Cartridge
- Optional Barcode Scanner
- IFU/Labeling

Sample Types:
The Nova Primary Glucose Analyzer System accepts lithium heparinized venous whole blood and plasma.

Intended Use:
Please see Indication for Use.

Indication for Use:
The Nova Primary Glucose Analyzer System is indicated for *in vitro* diagnostic use by healthcare professionals in clinical laboratory settings for the quantitative determination of Glucose in lithium heparinized venous whole blood and plasma.

The measurement of Glucose is used in the diagnosis and treatment of carbohydrate metabolism disturbances including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and pancreatic islet cell carcinoma.

Summary of the Technological Characteristics:
The Nova Primary Glucose Analyzer was designed to be substantially equivalent in performance to the predicate device, incorporating modern technology updates in the analyzer platform.

The Nova Primary Glucose Analyzer utilizes a discrete, easily replaceable glucose sensor and membrane/cap assembly. Glucose measurement is conducted on diluted venous whole blood or plasma samples and is based on the enzymatic reaction between glucose and oxygen molecules in the presence of the glucose oxidase enzyme. All glucose measurement algorithms are intended to report plasma equivalent glucose results that are substantially equivalent to the predicate device plasma glucose result, and are traceable to isotope dilution mass spectrometry. For whole blood specimens, the Nova Primary Glucose Analyzer utilizes an impedance-based conductivity detector to automatically adjust glucose measurement and provide the plasma equivalent glucose value based on the conductivity of the sample.

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.

Summary of Performance Testing:
Testing was completed to show that the Nova Primary Glucose Analyzer demonstrates substantial equivalence to the YSI 2300 Stat Glucose and L-Lactate Analyzer. The performance testing included:

- Method Comparison Studies
- Precision/Reproducibility Studies
- Linearity Testing
- Specificity / Interference Testing
- Detection Limit
- Shelf Life Stability Testing

The results of the performance testing confirmed that the Nova Primary Glucose Analyzer demonstrates substantial equivalence to the YSI 2300 Stat Glucose and L-Lactate Analyzer.

Conclusion:
The results of software validation and performance verification testing confirmed that the Nova Primary Glucose Analyzer System demonstrates substantial equivalence to the YSI 2300 Stat Glucose and L-Lactate Analyzer (k891480 – predicate device).

Table 1: Comparison of Predicate and Proposed Devices

Characteristic	Predicate:	Proposed:
Intended/Indications for Use	The YSI 2300 STAT PLUS Glucose and Lactate Analyzer is a laboratory instrument intended for use in clinical care and sports medicine applications. It provides quick measurements of glucose in whole blood, plasma or serum; and of L-lactate in whole blood, plasma, or cerebrospinal fluid (CSF). In whole blood or plasma, glucose and L-lactate can be measured simultaneously.	The Nova Primary Glucose Analyzer System is indicated for *in vitro* diagnostic use by healthcare professionals in clinical laboratory settings for the quantitative determination of Glucose in lithium heparinized venous whole blood and plasma. The measurement of Glucose is used in the diagnosis and treatment of carbohydrate metabolism disturbances including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and pancreatic islet cell carcinoma.
Intended Users	Trained laboratory personnel	Same
Measured Tests	Glucose and Lactate	Glucose
Glucose Enzyme	Glucose Oxidase	Same
Acceptable Sample Types	Whole Blood, Plasma, Serum	Lithium Heparin Whole Blood or Plasma
Sample Size Requirement	25 microliters (aspirated volume)	Same
Physical Dimensions	10.0 x 14.0 x 14.0 inches	19.0 x 19.0 x 6.0 inches
Instrument Weight	25 pounds	Less than 30 pounds including the calibrator cartridge
Sample Tray	Available Option	Not available
Bar Code Scanner	Not available	Optional, wireless bar code scanner via internal USB dongle
Keyboard	Not available	Optional, wireless keyboard via internal USB dongle
Power Supply	110–120 VAC, 220-240 VAC 50–60 Hz 50 Watts nominal	100-240 VAC 47-63 Hz Less than 50 Watts
Automatic Whole Blood Hematocrit Correction	No – Hematocrit is independently measured on a whole blood specimen then manually entered into YSI 2300 to calculate equivalent plasma glucose value.	Yes – Contains an impedance-based Conductivity Detector. Whole blood samples are automatically adjusted to provide plasma equivalent glucose values based on the conductivity of the sample.
User Interface Display	Alpha Numeric Liquid Crystal Display with 20 membrane keypad	PCAP Color Touchscreen Display with icon based Graphical User Interface
Printer	Yes onboard 2 ¼” thermal printer	Yes, onboard 2” thermal printer
Communication Protocol	RS-232 serial port	Not available