February 23, 2024

Nova Biomedical Corporation
Abhinav Kulkarni
Regulatory Affairs Specialist-II
200 Prospect St.
Waltham, Massachusetts 02454

Re: K232075
Trade/Device Name: StatStrip Glucose Hospital Meter System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: PZI
Dated: October 26, 2023
Received: October 26, 2023

Dear Abhinav Kulkarni:

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.
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)*
K232075

Device Name
StatStrip Glucose Hospital Meter System

Indications for Use *(Describe)*
The StatStrip Glucose Hospital Meter System is intended for point-of-care, in vitro diagnostic, multiple-patient use for the quantitative determination of glucose in capillary finger stick, venous whole blood, arterial whole blood, neonate arterial whole blood, and neonatal heel stick specimens throughout all hospital and all professional healthcare settings, including patients receiving intensive medical intervention/therapy.

The system should only be used with single-use, auto-disabling lancing devices when performing a capillary finger stick or neonatal heel stick.

It is not intended for use with neonate cord blood specimens.

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

The StatStrip Glucose Hospital Meter System includes the following components:
- StatStrip Glucose Hospital Meter
- StatStrip Glucose Test Strips

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

510(K) Number: K232075

510(K) Owner: Nova Biomedical Corporation

Registration Number: 1219029

Address: 200 Prospect St.
Waltham, MA 02454 USA

Contact Person:
Abhinav Kulkarni
Regulatory Affairs Specialist - II
781-894-0080 x 1672 (Office)
akulkarni@novabio.com

Secondary Contact Person:
Bobby Zinck
Senior Manager, Regulatory Affairs
781-894-0800 x 1705 (Office)
bzinck@novabio.com

Date Prepared
October 26, 2023

Proprietary Name
StatStrip Glucose Hospital Meter System

Common or Usual Name
Blood Glucose Meter

Classification Name:

Classification Name	Regulation #	Class	Product Code	Panel
Prescription Use Blood Glucose Meter for Near-Patient Testing	862.1345	II	PZI	Clinical Chemistry

Predicate Device
The predicate device for this submission is the StatStrip Glucose Hospital Meter System (K181043).

Purpose for Submission:
The StatStrip Glucose Hospital Meter System previously cleared under K060345, K063821, K132121, K150281, and K181043 is being modified to a next-generation meter platform to incorporate a new ergonomic design, and a new Operating System (OS).

Device Description:
StatStrip Glucose Hospital Meter System:
The StatStrip Glucose Hospital Meter System is a hand-held testing device that works in conjunction with the StatStrip Glucose Test Strips to measure glucose in a whole blood sample. Meter operation is self-prompting using an illuminated color touch-screen Graphical User Interface (GUI).

StatStrip Glucose Test Strips:
The test strips contain a reaction layer that contains a glucose-enzyme (greater than 1.0 IU) and ferricyanide as a mediator. The test strip is touched to a drop of blood to initiate the test process.
The strip is designed such that when a drop of blood is touched to the end of the strip, the blood is drawn into the reaction space via capillary action. A simple one-step process provides a blood glucose result. Test strips will be sold in vials of 25 strips.

StatStrip Glucose Control Solutions:
The control solutions are aqueous assayed solutions containing buffered D-Glucose, viscosity-adjusting agent, preservatives and other non-reactive ingredients (dye). They contain no products of human origin. There are three levels of controls, (Level 1, Level 2 and Level 3). These solutions will be offered for sale separately from the meter.

StatStrip Glucose Linearity Solutions:
There are 5 levels of Linearity solutions containing buffered D-Glucose, viscosity-adjusting agent, preservatives and other non-reactive ingredients (dye). They contain no products of human origin. These solutions are offered separately from the system for users to verify the performance of the system.

Charging (Docking) Station:
The meter charging station is a stationary accessory used to recharge the meter. The charging station has one slot for the meter to be placed and charged wirelessly. The charging station should be located central to the patient care area being served by the meter (e.g., a nursing station). The data charging station must remain plugged in to a wall outlet for power.
The system still allows the charging station to be used to transfer data from the meter to a central workstation and allow meter setup information to be downloaded from the central workstation to the meter.

Intended Use:
The StatStrip Glucose Hospital Meter System is intended for point-of-care, in vitro diagnostic, multiple-patient use for the quantitative determination of glucose in capillary finger stick, venous whole blood, arterial whole blood, neonate arterial whole blood, and neonate heel stick specimens throughout all hospital and all professional healthcare settings, including patients receiving intensive medical intervention/therapy.

The system should only be used with single-use, auto-disabling lancing devices when performing a capillary finger stick or neonate heel stick.

It is not intended for use with neonate cord blood specimens.

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

The StatStrip Glucose Hospital Meter System includes the following components:
- StatStrip Glucose Hospital Meter
- StatStrip Glucose Test Strips

Summary of Performance Testing:
The following testing was completed to demonstrate that the StatStrip Glucose Hospital Meter System is substantially equivalent to the predicate device.

ACCURACY

This study validated the performance equivalency between the StatStrip Glucose Hospital Meter System and the predicate device by measuring glucose on deidentified venous whole blood samples from consented donors.

Three (3) StatStrip Glucose Hospital Meters and three (3) predicate devices were tested side-by-side using three (3) lots of glucose test strips. A total of hundred (100) venous whole blood samples with glucose concentrations ranging from 20-600 mg/dL were tested on all meters, and the results were compared with a reference analyzer.

The Bias or Bias% for each specimen was calculated against the reference value, and the results were also compared to the FDA Guidance for POC Device Acceptance Criteria (Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use, Guidance for Industry and Food and Drug Administration Staff, September 29, 2020).

Next Generation StatStrip Glucose Hospital Meter (Proposed Device)
Glucose concentrations < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 12 mg/dL	Within ± 15 mg/dL
33/36 (91.7%)	36/36 (100%)	36/36 (100%)	36/36 (100%)

Current Production StatStrip Glucose Hospital Meter (Predicate Device)
Glucose concentrations < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 12 mg/dL	Within ± 15 mg/dL
32/36 (88.9%)	36/36 (100%)	36/36 (100%)	36/36 (100%)

Next Generation StatStrip Glucose Hospital Meter (Proposed Device)
Glucose concentrations ≧ 75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 12 %	Within ± 15 %
205/264 (77.3%)	263/264 (99.6%)	264/264 (100%)	264/264 (100%)

Current Production StatStrip Glucose Hospital Meter (Predicate Device)
Glucose concentrations ≧ 75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 12 %	Within ± 15 %
211/264 (80.7%)	263/264 (99.6%)	264/264 (100%)	264/264 (100%)

Linear Regression Summary - Slope and Correlation Coefficient (r) Values

Condition	Slope	Intercept	Correlation Coefficient (r)
Proposed Device v YSI	0.9799	5.2357	0.9977
Predicate Device v YSI	0.9848	5.2164	0.9984
Proposed Device v Predicate Device	0.9935	0.3571	0.9978

In conclusion, the results of this study demonstrated that the correlation and performance of the StatStrip Glucose Hospital Meter System is equivalent to the predicate device and the reference analyzer for glucose measurements, exhibiting good overall clinical agreement between the systems.

METHOD COMPARISON AND PRECISION

This study was conducted to verify and validate the Method Comparison and Precision performance equivalency between the StatStrip Glucose Hospital Meter System and the predicate device.

In this study, three (3) lots of glucose test strips, five (5) StatStrip Glucose Hospital Meters and five (5) predicate devices were used. Seven (7) levels of deidentified venous whole blood samples from consented donors and five (5) levels of linearity solutions were tested on all meters in the study, and the test results were compared to whole blood glucose measured on the reference analyzer.

The Mean, SD or CV% were calculated for each linearity level and meter (n =60); the Bias or Bias% (between calculated Means for each meter type) was calculated for each venous whole blood level. In addition, linear regression curves were plotted for venous whole blood, comparing the StatStrip Glucose Hospital Meter System and the predicate device.

Precision:

Linearity Solutions/Samples

Linearity Levels		Predicate Device		Proposed Device	
	N	Mean	SD/%CV	Mean	SD/%CV
Level 1	60	20.2	0.96	20.4	0.85
Level 2	60	62.2	1.61	62.4	1.76
Level 3	60	116.4	2.43	116	2.58
Level 4	60	300.8	2.71	301.5	2.40
Level 5	60	505.6	3.04	508.1	3.78

Venous Whole Blood Samples

YSI		Predicate Device		Proposed Device	
Mean	N	Mean	SD/%CV	Mean	SD/%CV
49	60	49.7	2.75	49.1	2.32
88	60	90.1	2.79	88.8	3.36
156	60	154.4	3.66	156.1	3.23
263	60	263.9	3.05	265.9	3.09
371	60	364.0	3.04	363.0	2.69
458	60	456.5	2.80	453.0	2.01
531	60	535.9	2.37	532.1	1.73

Method Comparison/Accuracy:

Accuracy Data Summary (Venous Whole Blood Samples)

YSI Blood Glucose (mg/dL)	Lot 0322311249			Lot 0322325249			Lot 0322346249		
	Proposed Device Mean	Predicate Device Mean	Bias*/ Bias%	Proposed Device Mean	Predicate Device Mean	Bias*/ Bias%	Proposed Device Mean	Predicate Device Mean	Bias*/ Bias%
49	49.4	50.5	-1.2*	49.5	47.8	-0.3*	50.5	50.9	-0.4*
88	89.2	90.8	-1.6*	89.0	90.3	-1.3*	88.3	89.4	-1.1*
156	154.2	152.6	1.0%	156.1	153.8	1.5%	157.9	157.0	0.6%
263	264.0	260.3	1.4%	266.1	263.7	0.9%	267.7	267.6	0.0%
371	363.0	356.4	1.9%	362.4	366.0	-1.0%	363.6	369.7	-1.7%
458	453.0	456.4	-0.7%	450.5	453.4	-0.6%	455.6	459.6	-0.9%
531	533.5	536.5	-0.5%	529.9	533.9	-0.7%	533.1	537.4	-0.8%

Linear Regression:

Linear Regression Summary - Slope and Correlation Coefficient (r) Values

Condition	Slope	Intercept	Correlation Coefficient (r)
Predicate Device v YSI	0.9996	0.0936	0.9985
Proposed Device v YSI	0.9922	0.9900	0.9989
Proposed Device v Predicate Device	0.9902	1.755	0.9980

In conclusion, all the measurements passed the acceptance criteria, and the testing results confirmed that the performance of the StatStrip Glucose Hospital Meter System is substantially equivalent to that of the predicate device.

Substantial Equivalence Information:
The StatStrip Glucose Hospital Meter System (K232075) is substantially equivalent in terms of intended use/indications for use, fundamental scientific technology, principle of operation, reagents used, performance claims/analytical test algorithms to the Statstrip Glucose Hospital Meter System (K181043) predicate device.

The table below provides a comparison between the currently released (predicate device) and the proposed device.

Characteristic	Predicate: StatStrip Glucose Hospital Meter System (K181043)	Proposed: StatStrip Glucose Hospital Meter System (K232075)
Intended Use	The StatStrip Glucose Hospital Meter System is intended for point-of-care, in vitro diagnostic, multiple-patient use for the quantitative determination of glucose in capillary finger stick, venous whole blood, arterial whole blood, neonate arterial whole blood, and neonate heel stick specimens throughout all hospital and all professional healthcare settings, including critical care settings. The system should only be used with single-use, auto-disabling lancing devices when performing a capillary finger stick or neonate heel stick. It is not intended for use with neonate cord blood specimens. It is not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia.	Same as Predicate
Environment Used	Hospital and all Professional healthcare settings, including critical care; Point-of-care settings	Same as Predicate
Measuring Range	10 - 600 mg/dL (or) 0.6 - 33.3 mmol/L	Same as Predicate
Hematocrit Range	20-70%*	Same as Predicate
Operating Principle	Electrochemical biosensor	Same as Predicate
Sample Type	Capillary whole blood (finger stick), venous whole blood, arterial whole blood, neonatal arterial whole blood samples, neonatal heel stick throughout all hospital and all professional healthcare settings, including critical care settings	Same as Predicate
Sample Size	1.2 µL	Same as Predicate
Sample Application	Test Strip capillary draw	Same as Predicate
Overall Design	Handheld Meter	Same as Predicate
Meter Calibration	Automatic, no calibration code	Same as Predicate
Data Storage	1500 patient tests, 4000 operator records	1500 patient tests, 8000 operator records 200 QC test results
Test Time	6 seconds	Same as Predicate
Test Strips - Active	Glucose oxidase	Same as Predicate

Characteristic	Predicate: StatStrip Glucose Hospital Meter System (K181043)	Proposed: StatStrip Glucose Hospital Meter System (K232075)
Measurement Technology	Enzyme, Amperometric Glucose Enzyme (Aspergillus sp., >1.0 IU)	Same as Predicate
Quality Controls	Liquid, 3 levels	Same as Predicate
Linearity	Liquid, 5 levels	Same as Predicate
Docking Station	Yes	Same as Predicate
Wireless Charging	No	Yes
Battery	Yes, 3.7V Li Polymer Battery (rechargeable) 1250 mAh	Yes, 3.6V Li Polymer Battery (rechargeable) 2200 mAh
Barcode Scanner	Yes	Same as Predicate
Wi-Fi Connectivity	Yes (802.11 for wireless communication)	Same as Predicate
Software Operating System (OS)	Windows CE	Linux
Dimensions	146 mm (5.8 in) x 79 mm (3.1 in) x 30 mm (1.18 in)	158 mm (6.23 in) x 77 mm (3.04 in) x 28 mm (1.11 in)
Weight	220 grams (0.49 lb)	215 grams (0.47 lb)
Temperature range	59°F - 104°F (15°C - 40°C)	Same as Predicate
Altitude	Up to 15,000 feet	Same as Predicate
Relative Humidity	Up to 90% (non-condensing)	Same as Predicate

**The Hematocrit Range for the StatStrip Glucose Hospital Meter System was established as 20-70% in K132121 and K181043 with the FDA.*

Conclusion

The performance testing study data results confirmed that the StatStrip Glucose Hospital Meter System (K232075) is safe and effective for its intended purpose. The StatStrip Glucose Hospital Meter System is substantially equivalent to the predicate StatStrip Glucose Hospital Meter System (K181043).