March 1, 2019

Nova Biomedical Corporation
Paul MacDonald
Chief Quality Assurance and Regulatory Affairs Officer
200 Prospect Street
Waltham, MA 02454-9141

Re: K150281
Trade/Device Name: StatStrip Glucose Hospital Meter
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: PZI
Dated: February 3, 2015
Received: February 5, 2015

Dear Paul MacDonald:

This letter corrects our substantially equivalent letter of May 6, 2015.

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 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150281

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 neonate heel stick specimens.

The StatStrip Glucose Hospital Meter System is also intended for use in the quantitative determination of glucose in venous whole blood, arterial whole blood, neonatal heel stick and neonatal arterial samples throughout all hospital and all professional healthcare 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.

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.

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510(k) Summary

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: Paul W. MacDonald

Date Prepared: April 21, 2015

Proprietary Name: StatStrip Glucose Hospital Meter System

Common or Usual Name: Glucose Oxidase, Glucose

Classification Name: Multiple

Classification Names:	**Class Panel No.**	**Reg. No.**	**Class**
Glucose Test System	75CGA	862.1345	II

Product Codes: CGA

Predicate Device: StatStrip Glucose Hospital Meter System, K060345, K063821, and K132121.

Device Description:

The StatStrip Glucose Hospital Meter System previously cleared under K060345, K063821, and K132121 is being modified to include a new ergonomic design and wireless (Wi-Fi) connectivity option. The new system, sold under a new ordering number with wireless option, contains the following:

1. StatStrip Meter, with integrated Wi-Fi connection and antenna option
2. Charging Station
3. Vial of StatStrip Test Strips
4. Battery (3.7 V Lithium)
5. Quick Reference Guide
6. Instructions for Use Manual
7. StatStrip Log Book

Offered separately:
- StatStrip Test Strips
- Quality Control solutions, Level 1, 2, 3
- Linearity Solutions, Levels 1,2,3,4,5

Meter
The StatStrip Glucose Hospital Meter is a hand-held testing device that works in conjunction with Nova glucose-test strips to measure glucose in a whole blood sample. Meter operation is self-prompting using an illuminated touch-screen Graphical User Interface (GUI). In addition to measuring glucose, the meter also stores patient test data, quality control test data and other information relating to the patient, patient sample, operator, reagents and meter.

The self-prompting menu system is navigated by means of a combination of touch-panel on-screen keys, on-screen soft keyboard. The operator can use a finger or a PDA style stylus to

select options for the on-screen display. It offers audible feedback for user inputs, and audible and/or visual feedback for prompts and user alerts. The Meter also has a barcode scanner that automates data entry.

The rechargeable batteries provide sufficient power to operate for 8 hours before requiring recharging. A “battery fuel gauge” bitmap constantly informs the user as to the current state of charge on the battery. Battery charge state information is available on the “meter Welcome screen”. The meter will shutoff (Sleep) after 90 seconds of inactivity. Test data and meter setup information will be stored in a non-volatile form to prevent data loss.

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 for charging and a slot for an extra battery to be charged.

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.

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.

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.

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.

Replacement batteries will be offered separately.

Wi-Fi Option

The StatStrip Glucose Hospital Meter with Wi-Fi option provides an additional communication method with a healthcare facility’s network system. This new Wi-Fi capability to transmit data results and other information using Radio Frequency is wholly unrelated to any of the existing technology and functionality, i.e., operations performed for the glucose measurement cycle are identical to the predicate device.

The design change of this new Wi-Fi communication method is offered on a new system as an option, i.e., the existing system without integrated Wi-Fi capability is still available. The primary difference between this new design and the cleared devices is an integrated Wi-Fi module using the IEEE 802.11 a/b/g communication protocol to transmit data.

This 510(k) submission contains information and study data associated with the Wi-Fi module option and ergonomic design enhancements, and shows the modified StatStrip Glucose Hospital Meter System is substantially equivalent to the predicate device.

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.

The StatStrip Glucose Hospital Meter System is also intended for use in the quantitative determination of glucose in venous whole blood, arterial whole blood, neonate heel stick and neonatal arterial samples throughout all hospital and all professional healthcare 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.

Summary of the Technological Characteristics:

The StatStrip Glucose Hospital Meter System with Wi-Fi option and new ergonomic design is substantially equivalent to the previously cleared StatStrip Glucose Hospital Meter System in intended use and technology. The new ergonomic meter design and Wi-Fi connectivity option do not introduce new concerns for safety and effectiveness. It uses the same sensor technology and measurement algorithms, and the formulations of the quality control and linearity solutions are identical.

Table 1: Comparison of Predicate and Proposed devices

Characteristic	Predicate Device: Nova StatStrip Hospital Glucose Meter (K060345, K063821, K132121)	Proposed: Device
Name	StatStrip Glucose Hospital Meter System	Same
Indication For Use/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. The StatStrip Glucose Hospital Meter System is also intended for use in the quantitative determination of glucose in venous whole blood, arterial whole blood, neonate heel stick and neonatal arterial samples throughout all hospital and all professional healthcare 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
Measuring Range	10-600 mg/dL	Same
Hematocrit Range	20-65%	Same
Operating Principle	Electrochemical biosensor	Same
Sample type	Capillary whole blood (finger stick), venous whole blood, arterial whole blood, neonate heel stick, and neonate arterial whole blood specimens Venous whole blood, arterial whole blood, neonatal heel stick, and neonatal arterial whole blood samples throughout all hospital and all professional healthcare settings	Same
Sample size	1.2 µL	Same
Sample application	Test strip capillary draw	Same
Handheld?	Yes	Same
Calibration	Automatic, no Calibration Code	Same
Data Storage	1,000 patient / 200 QC test results	Same
Test time to result	6 seconds	Same
Barcode scanner	Yes	Same
Power source	Rechargeable 3.7 volt Lithium battery	Same
Meter size and weight	153 mm (6.0 in) x 82.5 mm (3.25 in) x 46 mm (1.8 in) 266 grams (0.6 lb)	146 mm (5.8 in) x 79 mm (3.1 in) x

Characteristic	Predicate Device: Nova StatStrip Hospital Glucose Meter (K060345, K063821, K132121)	Proposed: Device
		30 mm (1.18 in) 220 grams (0.49 lb)
Test Strips – Active reagent:	Glucose Oxidase	Same
Quality Controls	Liquid, 3 levels	Same
Linearity	Liquid, 5 levels	Same
Docking Station?	Single station only	Single, dual, and quad stations
Strip ejector button	None	Yes
Wi-Fi Network Connectivity	None	Yes

Summary of Performance Testing:

Bench testing was completed to demonstrate that the modified StatStrip Glucose Hospital Meter System is substantially equivalent in performance, safety and efficacy to the currently cleared StatStrip Glucose Hospital Meter System (predicate device).

The internal bench testing included:

- Method Comparison Studies
- Precision Studies
- Cleaning and Disinfection

Additional external testing was conducted in intended use environments.

The results of the testing confirmed that the performance of the StatStrip Glucose Hospital Meter System with new ergonomic enhancements and Wi-Fi connectivity option is substantially equivalent to that of the StatStrip Glucose Hospital Meter System (predicate device).

Conclusion:

The results of software validation and performance verification testing confirmed that the StatStrip Glucose Hospital Meter System with new ergonomic enhancements and Wi-Fi connectivity option is safe and effective for its intended use and purpose and that the system is substantially equivalent to that of the predicate device.