March 1, 2019

Nova Biomedical Corporation
Paul MacDonald
Chief Quality Assurance & Regulatory Affairs Office
200 Prospect Street
Waltham, MA 02454

Re: K132121
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: August 26, 2014
Received: August 27, 2014

Dear Paul MacDonald:

This letter corrects our substantially equivalent letter of September 24, 2014.

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)*
K132121

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 whole blood 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.

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:

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"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

A. Date Prepared:

23 September, 2014

B. 510(K) Owner:

Nova Biomedical Corporation
200 Prospect St.
Waltham, MA 02454 USA
Contact Person: Paul W. MacDonald
Phone: 781-894-0800
Fax Number: 784-891-4806
Registration Number: 1219029

C. Device Information

1. Proprietary Name:

StatStrip Glucose Hospital Meter System

2. Common Or Usual Name:

Blood Glucose Meter

3. Classification Name:

System, Test, Glucose Oxidase

4. Classification:

Class II (assay)

5. Product Codes:

CGA, Glucose Oxidase, Glucose

6. Regulatory Section:

21 CFR 862.1345, Glucose Test System

7. Panel:

Clinical Chemistry (75)

D. 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, neonatal heel stick and neonatal arterial whole blood 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.

E. Device Description:

StatStrip Glucose Hospital Meter

The StatStrip Glucose Hospital Meter 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). 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. Meter setup options relating to authorized operators, reagent lots, QC preferences, and other operational settings are customizable. Data is transferred bi-directionally between the meter, data docking station, and separate data management system each time a meter is placed in to a data docking station.

Operator ID, patient ID, reagent lot number, test strip code, and sample accession number can be scanned into the meter using an optional built-in barcode scanner. The meter can store up to 1,000 patient test results and 200 quality control test results. The user can recall and sort or search the meter test results database to find specific test information. A rechargeable battery provides power to operate. A battery low warning will alert the user to recharge the battery. Battery charge state information is available on the "meter status screen". A System Manager selectable auto shutoff option is provided to conserve power when the meter is not in use. All test data is stored in a non-volatile form to prevent data loss.

Test Strips

The Test Strip is designed with an electrode that measures Glucose levels. Glucose in the blood sample mixes with reagent on the test strip that produces an electric current. The amount of current that is produced depends on how much Glucose is in the blood.

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 50 strips.

Control Solutions

Control Solutions are aqueous solutions that contain no products of human origin. The controls solutions are for use with the StatStrip family of meters. There are three (3) levels of control solutions (1, 2, and 3)

Linearity Standards

The StatStrip Glucose Linearity Solutions are aqueous materials with a known concentration of glucose intended to verify performance of the Nova Biomedical Analyzers. Assay values for expected ranges are included on every bottle of linearity standards. If the results obtained are outside the expected range, the system may not be performing correctly. The combined linearity solutions are for use with the StatStrip family of meters. There are five (5) Levels of Linearity Standards.

Data Docking Station

The meter Data Docking Station is a stationary accessory used to recharge the battery in the meter. The charging station has one slot for the meter to be placed for charging and additional slots for extra batteries to be charged.

The charging station is typically located central to the patient care area being served by the meter (e.g. a nursing station). The Data Docking Station must remain plugged in to a wall outlet for power.

The Data Docking Station is used to charge the meter and can be used with a USB cable to transfer data from the meter to a central workstation (i.e. Computer Database or a Data Capture System).

F. Summary of Technological Characteristics:

The StatStrip Glucose Hospital Meter System is the same device cleared in K063821 and K060345 (Nova StatStrip Glucose Hospital Meter System) and has the same scientific technology. No changes have been made to the meter, the software, the test strips, the controls or the linearity solutions. The only change is to the labeling for the device to allow the product to be used on arterial or venous samples on patients throughout all hospital and all professional healthcare settings. The StatStrip Glucose Hospital Meter System is substantially equivalent to the predicate Nova StatStrip Glucose Hospital Meter System.

G. Predicate Device:

K063821 – Nova StatStrip Glucose Hospital Meter System (add additional sample type)

H. Comparison to Predicate Devices:

The StatStrip Glucose Hospital Meter System is the exact same device as the Nova StatStrip Glucose Hospital Meter System cleared in K063821 and K060345. No changes have been made to any of the components of the system or software. The only difference is the addition of the indication to be used on venous and arterial samples on patients throughout all hospital and all professional healthcare settings.

I. Performance Studies:

The laboratory and clinical performance data for the StatStrip Glucose Hospital Meter System supports the expanded use of the system for arterial and venous specimens in all hospital and all professional healthcare settings.

J. Conclusion:

Results of clinical performance and laboratory testing demonstrate that the StatStrip Glucose Hospital Meter System produces results that are substantially equivalent to central laboratory methods when used as indicated in all hospital and all professional healthcare settings. The system performs as intended and raises no new safety or effectiveness issues.

Comparison of Predicate and Proposed device

Characteristic	Predicate – Nova StatStrip Glucose Hospital Meter System K063821	Proposed – StatStrip Glucose Hospital Meter System
Intended Use	The Nova StatStrip Glucose Hospital Meter System is intended for in vitro diagnostic use by healthcare professionals and for point-of-care usage in the quantitative determination of Glucose (GLU) in whole blood. Nova StatStrip Test Strips may be used to test capillary, venous, arterial and neonate blood samples. It is indicated for use in a clinical setting by healthcare professionals as an aid to monitor the effectiveness of diabetes control.	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 whole blood 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.
Test Measured	Glucose	Glucose
Operating Principle	Coulometric Electro-chemical Sensor	Coulometric Electro-chemical Sensor
GLU Measuring Range	10-600 mg/dL	10-600 mg/dL
Hematocrit Range	25% to 60%	25% to 60%
GLU Sample size	1.2 µL	1.2 µL
Glucose Units	mg/dL	mg/dL

Characteristic	Predicate – Nova StatStrip Glucose Hospital Meter System K063821	Proposed – StatStrip Glucose Hospital Meter System
Sample type	Whole Blood: Capillary, Venous Arterial and Neonate	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.
Sample application	Test strip capillary draw	Test strip capillary draw
Handheld meter	Yes	Yes
Data storage	1000 Patient Tests 200 QC Tests 4000 Operators	1000 Patient Tests 200 QC Tests 4000 Operators
GLU Analysis Time	6 seconds	6 seconds
Power source	Rechargeable Li 3.7 volt battery	Rechargeable Li 3.7 volt battery
GLU Test Strips Active reagent:	Glucose Oxidase	Glucose Oxidase
Accessories:		
Controls:	Liquid, 3 Levels	Liquid, 3 Levels
Linearity Sol	Liquid, 5 Levels	Liquid, 5 Levels