July 12, 2018

Nova Biomedical Corporation
John Mchale
VP of RA/QA and Technical Support
200 Prospect Street
Waltham, MA 02454

Re: K181043
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: April 18, 2018
Received: April 19, 2018

Dear John Mchale:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); 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,

Kellie B. Kelm -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

k181043

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 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.

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) Number: K181043

510(k) Owner: Nova Biomedical Corporation
Registration Number: 1219029
Address: 200 Prospect St.
Waltham, MA 02453
Fax Number: 784-891-4806
Contact Person: John F. Mchale
Phone: 781-894-0800
Date Prepared: July 3, 2018

Proprietary Name: StatStrip Glucose Hospital Meter System

Common or Usual Name: Blood Glucose Meter

Product Code: PZI

Classification Name:

Classification Name	Class No.	Regulation No.	Class
Prescription Use Blood Glucose Meter For Near-Patient Testing	75 PZI	862.1345	II

Predicate Device: StatStrip Glucose Hospital Meter System, K150281.

Device Description:

The StatStrip Glucose Hospital Meter System was previously cleared under K150281. The purpose of this dual 510(k) and CLIA Waiver submission for the StatStrip Glucose Hospital Meter System is to expand the indication for use to include the use of capillary specimens on patients receiving intensive medical intervention/therapy and support a CLIA Waived categorization for this expanded indication for use to include the quantitative determination of glucose in capillary finger stick throughout all hospital and all professional healthcare settings. No changes have been made to the device, the software, the test strips, controls or linearity solutions.

The system 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 StatStrip 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 provides a Wi-Fi communication method with a healthcare facility's network system. The wireless radio chipset utilizing the IEEE 802.11 a/b/g communication protocols (Wi-Fi) is used as an optional means to transmit and receive test results, previously cleared under K150281.

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.

Summary of the Technological Characteristics:

The StatStrip Glucose Hospital Meter System has the same scientific technology as the predicate. 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 of the device to allow the product to be used on capillary samples in critical care patient settings. The StatStrip Glucose Hospital Meter System is substantially equivalent to the StatStrip Glucose Hospital Meter System.

Summary of the Clinical Study Data:

Nova Biomedical conducted a large multi-center study of the StatStrip Glucose Hospital Meter System at two (2) leading medical centers to demonstrate the clinical performance of capillary whole blood specimens obtained by finger stick within critical care hospital settings on patients receiving intensive medical intervention/therapy. StatStrip capillary glucose specimens were compared to plasma glucose specimens obtained from either an arterial or venous specimen within 15 minutes of the capillary specimen as measured on a central laboratory comparator method. Clinical Study Site #1 was a CLIA Waived prospective study and the other 2 studies conducted in Site #2 and Site #3 were CLIA Waived retrospective studies designed to assess real world clinical performance throughout all hospital and all professional healthcare settings. Study **Site #1** and **#3** is one of the top ranked hospitals in Diabetes & Endocrinology located in Minnesota and study **Site #2** is one the world's preeminent healthcare institutions located in Maryland. A description of the clinical study is found below. All central laboratory comparisons were against an IDMS traceable hexokinase comparator method (Roche Cobas System, Roche Diagnostics, Indianapolis, IN).

Prospective Clinical Study

The prospective capillary critical care clinical study **(Site #1)** included 568 critical care patients undergoing intensive medical intervention/therapy within 3 critical care departments (CVICU, MICU and OR). The critical care patients from the CVICU and MICU included 80 unique patient conditions receiving a total of 3,785 medications representing 17 parent drug classes. Medical conditions and medications were unavailable for critical care patients in the OR.

Real World Evidence Studies

The purpose of these studies was to retrospectively data mine real world evidence on the performance of StatStrip glucose with capillary whole blood specimens obtained by skin puncture from adult and pediatric patients in Intensive Care Units (ICUs) on critically ill patients receiving Intensive Medical Intervention/Therapy as compared to plasma glucose obtained from either an arterial or venous specimen. These real world retrospective studies were conducted by CLIA Waived operators within these healthcare settings. The CLIA Waived operators were qualified to use the StatStrip system per institutional requirements in these critical care settings.

Real World Study Site Breakdown

Clinical **Study #2** was a real world clinical review of 2,133 critical care patients throughout all critical care settings that had a glucose test performed using a capillary whole blood specimen obtained by finger stick and a plasma glucose test obtained from either an arterial or venous specimen performed in the

central laboratory within 15 minutes of the capillary test. Medical conditions and medications were unavailable for critical care patients in this study.

Clinical **Study #3** was a real world clinical review of 14,645 critical care patients throughout all critical care settings that had a glucose test performed using a capillary whole blood specimen obtained by finger stick and a plasma glucose test obtained from either an arterial or venous specimen performed in the central laboratory within 15 minutes of the capillary test. Medical conditions and medications were unavailable for critical care patients in this study.

Clinical Study Performance

Study #1 (Prospective Study)

Fingertip capillary samples with glucose concentrations <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 12 mg/dL	Within ± 15 mg/dL	Exceeds ± 15 mg/dL
1/1 (100%)	1/1 (100%)	1/1 (100%)	1/1 (100%)	0/1 (0%)

Fingertip capillary samples with glucose concentration ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 12 %	Within ± 15 %	Within ± 20 %	Exceeds ± 20 %
277/567 (48.9%)	450/567 (79.4%)	484/567 (85.4%)	516/567 (91.0%)	549/567 (96.8%)	18/567 (3.2%)

Study #2 and #3 (Combined)

Fingertip capillary samples with glucose concentrations <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 12 mg/dL	Within ± 15 mg/dL	Exceeds ± 15 mg/dL
907/1894 (47.9%)	1470/1894 (77.6%)	1614/1894 (85.2%)	1737/1894 (91.7%)	157/1894 (8.3%)

Fingertip capillary samples with glucose concentration ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 12 %	Within ± 15 %	Within ± 20 %	Exceeds ± 20 %
7473/14884 (50.2%)	11807/14884 (79.3%)	12799/14884 (86.0%)	13712/14884 (92.1%)	14350/14884 (96.4%)	534/14884 (3.6%)

Comparison of Predicate and Proposed devices

Characteristic	Predicate Device: Nova StatStrip Hospital Glucose Meter (K150281)	Proposed: Device
Indication For 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.	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.
Measuring Range	10-600 mg/dL	Same as Predicate
Hematocrit Range	20-65%	Same as Predicate
Operating Principle	Electrochemical biosensor	Same as Predicate
Sample size	1.2 µL	Same as Predicate
Handheld meter?	Yes	Same as Predicate
Calibration	Automatic, no Calibration Code	Same as Predicate
Data Storage	1,500 patient or QC test results	Same as Predicate
Test time to result	6 seconds	Same as Predicate
Weight	8.8 ounces	Same as Predicate
Barcode scanner	Yes	Same as Predicate
Power source	Rechargeable 3.7 volt Lithium battery	Same as Predicate

Characteristic	Predicate Device: Nova StatStrip Hospital Glucose Meter (K150281)	Proposed: Device
Test Strips – Active reagent:	Glucose Oxidase	Same as Predicate
Quality Controls	Liquid, 3 levels	Same as Predicate
Linearity	5 levels	Same as Predicate
Docking Station?	Yes	Same as Predicate
Wi-Fi Network Connectivity	Yes	Same as Predicate
Software	Yes	Same as Predicate

Conclusion:

The results of the clinical study data confirmed that the StatStrip Glucose Hospital Meter System is safe and effective for its intended purpose. StatStrip Glucose Hospital Meter System is substantially equivalent to that of the predicate StatStrip Glucose Hospital Meter System (K15028).