December 13, 2018

Nova Biomedical Corporation
Khushboo Surendran
200 Prospect Street
Waltham, MA 02454

Re: K182552
Trade/Device Name: StatStrip Xpress Glucose Hospital Meter System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: PZI
Dated: September 14, 2018
Received: September 17, 2018

Dear Khushboo Surendran:

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/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,

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)*
K182552

Device Name
StatStrip Xpress Glucose Hospital Meter System

Indications for Use *(Describe)*
The StatStrip Xpress 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: K182552

510(k) Owner: Nova Biomedical Corporation
Registration Number: 1219029
Address: 200 Prospect St.
Waltham, MA 02454
Fax Number: 784-891-4806
Contact Person: Khushboo Surendran
Phone: 781-894-0800
Date Prepared: September 14, 2018

Proprietary Name: StatStrip Xpress 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, K181043.

Device Description:

The purpose of this submission is to change the labeling by expanding the indication for use statement to include the use of capillary whole blood specimens throughout all hospital and all professional healthcare settings, including patients receiving intensive medical intervention/therapy. This expanded indication was previously cleared for the predicate device, StatStrip Glucose Hospital Meter System in K181043.
No changes have been made to the candidate device, the software, the test strips, controls or linearity solutions since the clearance in K161856.

Meter:
The StatStrip Xpress Glucose Hospital Meter is a hand-held, battery-powered, in vitro diagnostic laboratory instrument that works in conjunction with Nova Biomedical glucose electrochemical test strips to measure glucose in a whole blood sample, Quality Control (QC), linearity, or proficiency solutions. In addition to measuring glucose, the meter stores patient test data, QC test data, and other information relating to patient, patient sample, operator, reagents, and the meter. The meter can store up to 400 patient and/or quality control test results. The user can review all stored test results on screen. Functions and data selection are accomplished by 3 push buttons. The meter has a built-in beeper for audible alerts and prompts.

Test Strips:
The StatStrip Glucose Hospital Meter Test Strips are intended for use with the StatStrip Xpress Glucose Hospital Meter System. No changes have been made to the form, fit, function or packaging of StatStrip Glucose Hospital Meter Test Strips since K070960 clearance and they are not a subject of this submission.

Control Solutions:
The Nova StatStrip Glucose Control Solutions are used as a quality control check to ensure that the StatStrip Xpress Glucose Hospital Meter and the Glucose Test Strips are working properly as a system.

No changes have been made to the form, fit, function or packaging of the Nova StatStrip Glucose Control Solution since K070960 clearance and they are not a subject of this submission.

Linearity Solutions:
The Nova StatStrip Glucose Linearity Solutions are used to check the linearity of the Nova StatStrip Xpress Glucose Hospital Meter. No changes have been made to the form, fit, function or packaging of the Nova StatStrip Glucose Linearity Solution since K070960 clearance and they are not a subject of this submission.

Principle of Test
The Test Strip is designed with an electrode that measures glucose levels. Glucose (sugar) 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 StatStrip Xpress Glucose Hospital Meter System with StatStrip Glucose Hospital Meter Test Strip measures the glucose level in blood. The glucose result is displayed on the screen of the meter. The test strip is calibrated against plasma.

Intended Use:

The StatStrip Xpress 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 Xpress Glucose Hospital Meter System uses the exact same technology, operating principle, software measurement algorithm and user workflow as the predicate device, StatStrip Glucose Hospital Meter System (K181043).

The StatStrip Xpress Glucose Hospital Meter System was recently cleared under K150461 by demonstrating substantially equivalent performance to the StatStrip Glucose Hospital Meter System.

The only proposed change is to the labeling of the device to allow the product to be used on capillary whole blood specimens throughout all hospital and all professional healthcare settings, including patients receiving intensive medical intervention/therapy.

Comparison of Predicate and Candidate devices

Item	Predicate Device (K181043) StatStrip Glucose Hospital Meter System	Candidate Device StatStrip Xpress Glucose Hospital Meter System
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 Xpress 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.
Operating Principle	Electrochemical biosensor	Same
Measuring Technology	Enzyme, Amperometric Glucose Enzyme (Aspergillus sp., >1.0 IU)	Same
Sample type	Capillary whole blood (finger stick), venous whole blood, arterial whole blood, neonatal heel stick, and neonatal arterial whole blood samples	Same
Sample size	1.2 µL	Same
Sample application	Test strip capillary draw	Same
Measuring range	10-600 mg/dL	Same
Hematocrit range	20-65%	Same

Item	Predicate Device (K181043) StatStrip Glucose Hospital Meter System	Candidate Device StatStrip Xpress Glucose Hospital Meter System
Reported output	mg/dL	Same
Time to Result	~ 6 seconds	Same
Calibration	Automatic, no Calibration Code	Same
Test strip active reagent	Glucose Oxidase	Same
Quality Control	3 levels	Same
Linearity	5 levels	Same
Handheld	Yes	Same
Data storage	1000 patient tests, 200 QC tests, 4000 Operators	400 patient, quality control, linearity, and proficiency tests
Barcode	Yes	No
Power source	Rechargeable 3.7 volt Lithium battery	3v dc Li coin cell battery
Operating Temp	59°F - 104°F (15°C - 40°C)	41° to 104°F (5° to 40°C)

Conclusion:

FDA had previously determined that the StatStrip Xpress Glucose Hospital Meter System is substantially equivalent to that of the predicate StatStrip Glucose Hospital Meter System (K070960, K152461). The expanded indication proposed in this submission was previously cleared for the predicate device (K181043). No changes have been made to the candidate device, the software, the test strips, controls or linearity solutions since the K161856 clearance therefore; there are no additional safety and efficacy concerns to the device.

The candidate device with the proposed revised labeling is substantially equivalent to the predicate StatStrip Glucose Hospital Meter System (K181043), and supports a CLIA waiver designation.