March 1, 2019

Nova Biomedical Corporation
Paul MacDonald
200 Prospect Street
Waltham, MA 02454

Re: K152986
Trade/Device Name: StatStrip Xpress 2 Glucose Hospital Meter System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: PZI
Dated: December 22, 2015
Received: December 28, 2015

Dear Paul MacDonald:

This letter corrects our substantially equivalent letter of January 27, 2016.

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)*

Device Name
StatStrip Xpress 2 Glucose Hospital Meter System

Indications for Use *(Describe)*

The StatStrip Xpress 2 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 Xpress 2 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: September 30, 2015

Proprietary Name: StatStrip Xpress 2 Glucose Hospital Meter System

Common or Usual Name: Blood Glucose Meter

Regulatory Information:

Regulatory Panel: Clinical Chemistry
Regulatory Number: 21CFR 862.1345
Device Class: II
Product Code: CGA, Glucose Oxidase, Glucose

Predicate Device: K150461-StatStrip Xpress Glucose Hospital Meter System

Device Description:

The StatStrip Xpress Glucose Hospital Meter System previously cleared under K070960 and K150461 is being modified to include a 2.2 inch color graphics display and an updated ergonomic design. The new system will be sold as the StatStrip Xpress 2 Glucose Hospital Meter System.

The intended use of the modified StatStrip Xpress 2 Glucose Hospital Meter System has not changed as a result of the modifications.

The StatStrip Xpress 2 Glucose Hospital Meter utilizes a 2.2" color graphics display in place of the segmented display that is currently used in the predicate StatStrip Xpress Glucose Hospital Meter. The color screen allows for the user interface to be displayed in a more modern format; however the overall screen content of the meter will remain unchanged from the predicate device. The StatStrip Xpress 2 Glucose Hospital Meter will utilize the same screen progressions and user workflow as the predicate device. The StatStrip Xpress 2 Glucose Hospital Meter utilizes the same three button keypad design as the predicate to navigate the user interface.

To support the increased power requirements of the color display, the newly designed StatStrip Xpress 2 Glucose Hospital Meter will be powered by two AAA batteries in place of the single Li 2450 coin cell battery used in the predicate StatStrip Xpress Glucose Hospital Meter.

The StatStrip Xpress 2 Glucose Hospital Meter uses identical signal processing and results generating methods and stores test results in the same manner as the predicate device.

The StatStrip Xpress 2 Glucose Hospital Meter's new ergonomic design introduces a flat, top surface design that eliminates ridges, recessed corners and raised edges. The strip port has been moved to the bottom of StatStrip Xpress 2 Glucose Hospital Meter in order to increase customer satisfaction. The new location of the strip port reduces the chance of control material entering the strip port. The StatStrip Xpress 2 Glucose Hospital Meter utilizes the same strip port and front end electronics for making glucose measurements as the predicate device. The proposed device has the same performance characteristics as the predicate device.

Meter

The StatStrip Xpress 2 Glucose Hospital Meter System is specifically designed to meet the bedside and point-of-care glucose testing needs in today's hospital environment. The system is intended for in vitro diagnostic use by health care professionals for both clinical and point-of-care usage for the quantitative determination of glucose in whole blood. It is intended to provide plasma equivalent results to laboratory methods. The StatStrip Xpress 2 Glucose Hospital Meter System is intended for use in a clinical setting by healthcare professionals as an aid to monitor glucose levels in the management of dysglycemia. The StatStrip Xpress 2 Glucose Hospital Meter is a hand-held testing device that works in conjunction with the StatStrip Glucose Test Strips. Meter operation is self-prompting using a new 2.2 inch color graphics display. Function and data selection is accomplished using 3 push buttons. The handheld meter supports audible alerts and prompts with a built-in beeper. In addition to measuring glucose, the meter also stores up to 400 patient test records. The user can recall and review test results.

Two AAA batteries power the device, and are expected to perform up to 600 tests before needing to be replaced. A low battery prompt will appear when it is time to replace the battery. All test data is stored in a non-volatile form to prevent data loss.

Test Strips

The StatStrip Glucose Hospital Meter Test Strips that are the subject of this submission are identical in form, fit, function and packaging, to the glucose test strips currently cleared for use with the StatStrip Xpress Glucose Hospital Meter System (K070960, K150461). 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 cartons of 100 strips (50 strips/vial).

Contents:

Each glucose test strips contain a reaction layer that contains glucose enzyme (Aspergillus sp.) >1.0 IU, mediator ≥ 20 µg, and other nonreactive substances.

Function:

StatStrip Glucose Test Strips are intended for quantitative determination of Glucose in fresh whole blood specimens. StatStrip Glucose Test Strips are for use only with the StatStrip Family of Meters.

Storage Conditions:

Store the test strips in the vial between 34-86°F (1-30°C). Ensure that the vial is closed between uses. Once opened the test strips in the vial may be used for 180 days or until the expiration date printed on the label, whichever comes first.

Controls and Linearity Solutions

The StatStrip Control and Linearity Solutions that are intended for use with the system are identical in formulation and packaging, to the Control and Linearity Solutions originally cleared for use with the StatStrip Xpress Glucose Hospital Meter System in K070960.

Control Solutions

The StatStrip Control Solutions are aqueous solutions that contain no products of human origin. The controls solutions are for use with all of the StatStrip Meters.

Contents:

Each vial contains approximately 4mLs of a buffered aqueous control solution containing glucose, β-ketone, preservative, viscosity-adjusting agent and other non-reactive ingredients (dye).

There are three levels of control solutions (Levels 1-3).

Function:

StatStrip Glucose Control Solutions are intended to verify the accuracy of the blood Glucose test results.

Storage Conditions:

Store the control solution in the vial at room temperature; 59°F-86°F (15°C-30°C). Ensure that the vial is closed between use. Once opened the control solution may be used for up to 3 months or until the expiration date printed on the label, whichever comes first.

Linearity Solutions

The StatStrip Glucose Linearity Solutions are aqueous materials with a known concentration of glucose intended to verify performance of the StatStrip Meters.

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.

Contents:

Each vial contains 4mLs of a buffered glucose, β-ketone, preservative, viscosity-adjusting agent and other non-reactive ingredients (dye). They contain no products of human origin.

There are five levels of linearity solutions (Levels 1-5).

Function:

The Linearity Solution is intended for monitoring the performance (linearity) of the StatStrip Glucose Hospital Meter System.

Storage Conditions:

Store the linearity solution in the vial at room temperature; 59°F-86°F (15°C-30°C). Ensure that the vial is closed between uses. Once opened the control solution may be used for up to 3 months or until the expiration date printed on the label, whichever comes first.

Intended Use:

The StatStrip Xpress 2 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 Xpress 2 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.

Summary of the Technological Characteristics:

The StatStrip Xpress 2 Glucose Hospital Meter System is substantially equivalent to the previously cleared StatStrip Xpress Glucose Hospital Meter System in intended use and technology. All test results are stored and recalled in the same manner as the predicate device. The new meter design and color screen do not introduce new concerns for safety and effectiveness. It uses the same sensor technology, measurement electronics and measurement algorithms, and the formulations of the glucose test strips, quality control and linearity solutions are identical.