March 1, 2019

Nova Biomedical Corporation
Paul MacDonald
Senior Director of Regulatory Affairs
200 Prospect Street
Waltham, MA 02454

Re: K163490
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 9, 2016
Received: December 12, 2016

Dear Paul MacDonald:

This letter corrects our substantially equivalent letter of January 6, 2017.

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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"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

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: **December 9, 2016**

Proprietary Name: StatStrip Xpress 2 Glucose Hospital Meter System

Common or Usual Name: Blood Glucose Meter

Classification Name:

Classification Names:	Class No.	Reg. No.	Class
Glucose Oxidase	75CGA	862.1345	II

Product Codes: CGA, Glucose Oxidase, Glucose

Predicate Device: K152986 - StatStrip Xpress 2 Glucose Hospital Meter System

Device Description:
The Nova Biomedical StatStrip Xpress 2 Glucose Hospital Meter System consists of a hand held meter, test strips, control solutions, and linearity solutions. The test strip contains a reagent (glucose oxidase) that reacts with the glucose in the test sample. The sample is applied to the test strip, which is then analyzed in the meter. The reagent test strip contains glucose oxidase and glucose dehydrogenase, which reacts with the glucose in the test sample.

A test strip is inserted into the meter, and the sample is applied to the sample entry end of the strip. When enough sample has been added to the strip (sample is drawn into strip though capillary action) the meter begins its analysis. A digital readout is displayed on the meter in 6 seconds. The system is designed for hospital point of care (POC) use including physicians' office labs.

Test Strips:

The StatStrip Glucose 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.

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 predicate device. The modification of the lower limit of the operating temperature range from 15°C to 5°C does not adversely affect the safety or efficacy of the device.

Table 1: Comparison of Predicate and Proposed Devices

Characteristic	Predicate: StatStrip Xpress 2 Glucose Hospital Meter System (K152986)	Proposed: StatStrip Xpress 2 Glucose Hospital Meter System
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.	Same as Predicate
Measuring Range	10-600 mg/dL	Same as Predicate
Hematocrit Range	20-70 %	Same as Predicate
Operating Principle	Electrochemical biosensor	Same as Predicate
Operating Temperature Range	59-104°F (15-40°C)	41-104°F (5-40°C)
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 as Predicate
Sample size	1.2 uL	Same as Predicate
Sample application	Test strip capillary draw	Same as Predicate
Handheld meter?	YES	Same as Predicate
Meter Calibration	Automatic, no Calibration Code	Same as Predicate
Data storage	400 test results	Same as Predicate
Test Time	6 sec	Same as Predicate
Weight	2.77 oz.	Same as predicate
Bar code scanner	None	Same as Predicate
Power source	Two AAA Batteries	Same as predicate
Controls:	Liquid, 3 levels	Same as Predicate
Linearity Solutions	Liquid, 5 levels	Same as Predicate
Test Strips – Active reagent:	Glucose Oxidase	Same as predicate
Screen Type	Non segmented Color Display	Same as predicate
Location of Strip Port	Bottom of Meter	Same as predicate