



NOVA BIOMEDICAL CORPORATION
ELIZA WANG
SENIOR REGULATORY AFFAIRS SPECIALIST
200 PROSPECT STREET
WALTHAM MA 02454

June 23, 2016

Re: K160156

Trade/Device Name: StatStrip Xpress Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: May 11, 2016
Received: May 12, 2016

Dear Ms. Eliza Wang:

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 Parts 801 and 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Katherine Serrano -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

Indications for Use

510(k) Number (if known)

K160156

Device Name

StatStrip Xpress Blood Glucose Monitoring System

Indications for Use (Describe)

The StatStrip Xpress Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood obtained from the fingertip. It is intended for single-patient home use and should not be shared. It is intended for self-testing outside the body by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes, and it is not intended for use with neonates.

The StatStrip Xpress Blood Glucose Monitoring System comprises the StatStrip Xpress Blood Glucose Monitor, StatStrip Xpress Glucose Test Strips, and StatStrip Xpress Glucose Control Solutions. The StatStrip Xpress Glucose Control Solutions are intended for use with the StatStrip Xpress Blood Glucose Monitoring System as a quality control check to verify the accuracy of blood glucose test results. There are 3 levels of controls (Levels 1, 2, and 3).

- The StatStrip Xpress Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use).

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.

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510(k) Summary

510(K) Owner: Nova Biomedical Corporation
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Contact Person: Eliza Wang, RAC
Senior Regulatory Affairs Specialist
Date Prepared: January 21, 2016

Proprietary Name: StatStrip Xpress Blood Glucose Monitoring System

Common or Usual Name: System, test, blood glucose, over the counter

Classification Name: Glucose test system

Class Panel: 75

Regulation Number: 21CFR 862.1345 & 862.1660

Product Code: NBW, JJX, CGA

Class: II, I (reserved), II

Predicate Device: Nova Max Blood Glucose Monitor System, K070255

Reference Device: StatStrip Xpress Glucose Hospital Meter System, K150461

Device Description:

The StatStrip Xpress Blood Glucose Monitoring System consists of a hand held StatStrip Xpress Blood Glucose Monitor, StatStrip Xpress Glucose Test Strips, StatStrip Xpress Glucose Control Solutions (Levels 1, 2, and 3, sold separately), Instructions for Use Manual, and Quick Reference Guide.

The StatStrip Xpress Blood Glucose Monitoring System is identical in fit, form, and function to the StatStrip Xpress Glucose Hospital Meter System which was previously cleared in K150461. The Blood Glucose Monitor, Test Strip, and Control Solutions for both the StatStrip Xpress Blood Glucose Monitoring System (subject device) and StatStrip Xpress Glucose Hospital Meter System (reference device) are identical. The only difference between them is the intended use and labeling. The StatStrip Xpress Glucose Hospital Meter System was cleared in K150461 for use with critical care patients. This submission is to expand the intended use of Nova's StatStrip Xpress

Glucose Meter System to include Over-the-Counter (OTC) use for single-patient home use.

The predicate device Nova Max Blood Glucose Monitoring System (K070255) was intended for OTC/home use.

As demonstrated in Table 2-1 below, the StatStrip Xpress Blood Glucose Monitoring System has the same intended use as the Nova Max Blood Glucose Monitor System. In addition, they are the same in the following characteristics:

- The Glucose Methodology: Glucose Oxidase Biosensor
- Test results: mg/dL, plasma equivalent values
- Sampling types : capillary whole blood obtained from the fingertip
- The size and weight
- The power source
- The monitor data storage

The major difference between the subject device and the predicate device is in their test strips. The Nova Max Blood Glucose Test Strips have two measurement wells; while the StatStrip Xpress Glucose Test Strips have four measurement wells. Both test strips utilize a Reference well and a Glucose measurement well. The two additional wells designed into the StatStrip Xpress Glucose Test Strips measure and correct for Electrochemical Interferences and Hematocrit. The improved design of the StatStrip Xpress Glucose Test Strip provides increased glucose measurement accuracy even under variable electrochemical interferences and hematocrit extremes. Therefore, the test range and acceptable Hematocrit range are different between the two systems as stated in the Table 2-1.

The StatStrip Glucose Test Strip reacts with the glucose in the test sample. The reaction produces an electrical current which is proportional to the amount of glucose in the sample, and the electrical current is detected by the monitor and displayed to the user as a glucose value.

Three levels of control solutions (Level 1, Level 2, and Level 3) are available for use with the StatStrip Xpress Blood Glucose Monitoring System and these were previously cleared in K150461.

Intended Use:

The StatStrip Xpress Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood obtained from the fingertip. It is intended for single-patient home use and should not be shared. It is intended for self-testing outside the body by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes, and it is not intended for use with neonates.

The StatStrip Xpress Blood Glucose Monitoring System comprises the StatStrip Xpress Blood Glucose Monitor, StatStrip Xpress Glucose Test Strips, and StatStrip Xpress Glucose Control Solutions. The StatStrip Xpress Glucose Control Solutions are intended for use with the StatStrip Xpress Blood Glucose Monitoring System as a quality control check to verify the accuracy of blood glucose test results. There are 3 levels of controls (Levels 1, 2, and 3).

- The StatStrip Xpress Blood Glucose Monitoring System is intended for use outside the body (*in vitro* diagnostic use).

Summary of the Technological Characteristics:

StatStrip Xpress Blood Glucose Monitoring System:

The StatStrip Xpress Blood Glucose Monitoring System (subject device) is identical in form, fit and function to the reference device StatStrip Xpress Glucose Hospital Meter System cleared in K150461 with the exception of new labeling for home use. The StatStrip Xpress Blood Glucose Monitoring System will be offered for self-testing in the home environment. The system is intended for *in vitro* diagnostic use by lay people for the quantitative determination of glucose in capillary whole blood obtained from the fingertip. It is intended to provide plasma equivalent glucose results to laboratory methods.

The StatStrip Xpress Blood Glucose Monitor:

The StatStrip Xpress Blood Glucose Monitor is a hand-held testing device that works in conjunction with the StatStrip Xpress Glucose Test Strips. Monitor operation is self-prompting using a segmented liquid crystal display (LCD) and icons. Function and data selection is accomplished using 3 push buttons. The handheld monitor supports audible alerts and prompts with a built-in beeper. In addition to measuring glucose, the meter also stores up to 400 test records for user to recall and review test results.

A single coin battery powers the device, and is expected to perform up to 600 tests before replacement. 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 Xpress Glucose Test Strips are identical in form, fit, function and packaging, to the glucose test strips cleared for use with the system in K150461 with the exception of new labeling for home use. 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 test 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 well via capillary action. A simple one-step process provides a blood glucose result.

Contents:

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

Function:

StatStrip Xpress Glucose Test Strips are intended for the quantitative determination of Glucose in fresh whole blood specimens. StatStrip Xpress Glucose Test Strips are for use only with the StatStrip Xpress Blood Glucose Monitoring System.

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 Solutions

The StatStrip Xpress Glucose Control Solutions that are intended for use with the system are identical in formulation and packaging, to the Control Solutions originally cleared for use with the system in K150461.

The StatStrip Xpress Glucose Control Solutions are intended for use with the StatStrip Xpress Blood Glucose Monitoring System as a quality control check to verify the accuracy of blood glucose test results. There are 3 levels of controls (Level 1, 2, 3).

Contents:

Each vial of StatStrip Xpress Glucose Control Solution 0.1 oz (4ml) contains:

- D-Glucose
- Preservative
- Blue dye
- Viscosity-adjusting agent

The contents are same for 3 Levels controls (Level 1, 2, 3).

Function:

The StatStrip Xpress Glucose Control Solutions are intended for use with the StatStrip Xpress Blood Glucose Monitoring System as a quality control check to verify the accuracy of blood glucose test results. There are 3 levels of controls (Level 1, 2, 3).

Storage Conditions:

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

Table 2-1: Comparison of Predicate and Proposed devices

Characteristic	Predicate Device (K070255)	Proposed Device (This submission)
	Nova Max Blood Glucose Monitor System	StatStrip Xpress Blood Glucose Monitoring System
Intended Use	<p>The Nova Max Blood Glucose Monitor System is intended to be used for the quantitative measurement of glucose in capillary whole blood. It is intended for use by people with diabetes mellitus <u>in the home</u> as an aid to monitor the effectiveness of diabetes control. The Nova Max Blood Glucose Monitor System is specifically indicated for the quantitative measurement of glucose in whole blood capillary samples obtained from the fingertip, palm and forearm.</p> <ul style="list-style-type: none"> • The Nova Max Blood Glucose Monitor System is intended for use outside the body (<i>in vitro</i> diagnostic use). • It should only be used with Nova Max Glucose Test Strips and Nova Max Glucose Control Solution. • It should be used for testing glucose (sugar) and only with fresh capillary whole blood samples. • It should NOT be used to diagnose diabetes or to test newborns. • It should NOT be stored in the refrigerator or in the car. 	<p>The StatStrip Xpress Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood obtained from the fingertip. It is intended for single-patient <u>home use</u> and should not be shared. It is intended for self-testing outside the body by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes, and it is not intended for use with neonates.</p> <p>The StatStrip Xpress Blood Glucose Monitoring System comprises the StatStrip Xpress Blood Glucose Monitor, StatStrip Xpress Glucose Test Strips, and StatStrip Xpress Glucose Control Solutions. The StatStrip Xpress Glucose Control Solutions are intended for use with the StatStrip Xpress Blood Glucose Monitoring System as a quality control check to verify the accuracy of blood glucose test results. There are 3 levels of controls (Levels 1, 2, and 3).</p> <ul style="list-style-type: none"> • The StatStrip Xpress Blood Glucose Monitoring System is intended for use outside the body (<i>in vitro</i> diagnostic use).
Common name	System, test, blood glucose, over the counter	Same

Characteristic	Predicate Device (K070255)	Proposed Device (This submission)
	Nova Max Blood Glucose Monitor System	StatStrip Xpress Blood Glucose Monitoring System
Product Code(s)	NBW, CGA, and JJX	Same
Regulation number	21 CFR §862.1345 and §862.1660	Same
Class	II	Same
Enzyme	Glucose Oxidase	Same
Operating Principle	Electrochemical biosensor, amperometric	Same
Sample type	Capillary whole blood capillary samples from the fingertip and alternative sites (palm and forearm).	Capillary whole blood from fingertip
Sample size	0.3 µL	1.2 µL
Sample application	Test Strip capillary draw	Same
Measuring range	20-600 mg/dL	Same
Hematocrit range	25-60%	20-65%
Reported output	mg/dL	Same
Time to Result	~ 5 seconds	~ 6 seconds

Characteristic	Predicate Device (K070255)	Proposed Device (This submission)
	Nova Max Blood Glucose Monitor System	StatStrip Xpress Blood Glucose Monitoring System
Quality control	3 levels	Same
Handheld	Yes	Same
Test Strip	2 wells	4 wells
Calibration	Automatic, no calibration code	Same
Data storage	400 test results	Same
Barcode	No	Same
Power source	3v Lithium coin cell battery	Same
Dimensions	3.6x2.3x0.9 in (91.4x58.4x22.9 mm)	Same
Weight	2.65 ounces (75grams)	same

Summary of Performance Testing:

Clinical Study

An external lay person clinical study was conducted at one site by one principal investigator. The clinical study was approved by the sites Institutional Review Board (IRB).

A total of 360 different StatStrip Xpress Blood Glucose Monitors were used in the clinical study by 360 different subjects. There was no sharing of monitors between subjects during the study. The subjects only received draft labeling and were asked to perform the testing steps in the study protocol without any additional coaching or training on the use of the subject device. A minimum of 10% of the subjects enrolled in the study defined themselves as a naïve user.

Three (3) different StatStrip Xpress Glucose test strip lots were used in the study. The 360 subjects were divided into three test groups (each 120 subjects). Each group of subjects utilized one of three assigned lots of the test strips. The test strips utilized by each subject group were used from at least 10 different test strip vials of each lot.

Prior to the start of the clinical study, the three lots of test strips used in the clinical study were exposed to typical shipping and handling conditions one would expect to the test strips to be exposed to having been shipped from Waltham, MA, to the external site.

Clinical study accuracy was assessed two ways 1.) ISO 15197:2003 Acceptance Standard that is currently used by the U.S. Food and Drug Administration and 2) the FDA Draft Guidance Standard for Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use that was issued on January 7, 2014. This standard remains in draft form as of the date of this submission.

1) ISO 15197:2003 Acceptance Standard

Acceptance Criteria: 95% of the reported glucose values must be within 15 mg/dL of the reference method when reference values are <75 mg/dL; and within 20% of the Yellow Springs International (YSI) reference method when ≥ 75 mg/dL.

System Accuracy for Glucose Concentrations <75 mg/dL

Within 5 mg/dL	Within 10 mg/dL	Within 15 mg/dL
6/14 (42.9%)	12/14 (85.7%)	14/14 (100%)

System Accuracy for Glucose Concentrations ≥ 75 mg/dL

Within 5%	Within 10%	Within 15%	Within 20%
110/346 (31.8%)	310/346 (89.6%)	338/346 (97.7%)	346/346 (100%)

Conclusion: The StatStrip Xpress Glucose Monitoring System met the ISO 15197:2003 acceptance criteria on 100% (360/360) of the specimens as measured by lay person subjects when compared to the YSI reference method.

2) FDA Draft Guidance Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use dated January 7, 2014 Acceptance Standard

Acceptance Criteria: 95% of the reported glucose values must be within 15% of the reference method and 99% of values must be within 20% of the YSI reference method.

System Accuracy for All Glucose Concentrations:

Within 5%	Within 10%	Within 15%	Within 20%
281/360 (78.1%)	338/360 (93.9%)	344/360 (95.6%)	360/360 (100%)

Conclusion: The StatStrip Xpress Blood Glucose Monitoring System met the draft U.S. FDA January 2014 OTC Guidance Acceptance Criteria with 95.6% of the specimens reporting glucose results within 15% of the YSI reference method and 100% of the specimens reporting glucose results within 20% of the YSI reference method. There were no results reported during the clinical study that were outside of 20% of the reference method.

Simplicity of Use Questionnaire:

Each Layperson subject subsequently answered a 26-question Simplicity of Use Questionnaire. Response to each question has a scale 1 to 5, with higher scale meaning easier usage of the monitor. The average response to the 26 questions, fell between “Neutral” (scale 3) and “Agree” (scale 4), with an average range of 3.3 to 3.6 across all questions. The responses to the questionnaire indicate that the participants were comfortable with the StatStrip Xpress Glucose Monitoring System, and lead to the conclusion that a typical layperson will find the monitor easy to operate, and the labeling easy to understand.

Conclusion:

The results of clinical testing confirmed that the StatStrip Xpress Blood Glucose Monitoring System is safe and effective for its intended use (OTC use) and the StatStrip Xpress Blood Glucose Monitoring System is substantially equivalent to the predicate device.