November 7, 2017

Nova Biomedical Corporation
Eliza Wang
Regulatory Affairs Project Manager
200 Prospect Street
Waltham, Massachusetts 02454

Re: K170464
Trade/Device Name: StatStrip Xpress Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: October 4, 2017
Received: October 5, 2017

Dear 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 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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)*
K170464

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 and StatStrip Xpress Glucose Test Strips.

• 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary for K170464

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:	Eliza Wang, RAC Regulatory Affairs Project Manager
Date Prepared:	**November 3rd, 2017**
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 No.	75
Regulation Number:	21 CFR 862.1345
Product Codes:	**NBW**
Class:	**II**
Predicate Device:	**StatStrip Xpress Blood Glucose Monitoring System, K160156**

Device Description:

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

The modified StatStrip Xpress Blood Glucose Monitoring System is identical in fit, form, and functions to the StatStrip Xpress Blood Glucose Monitoring System, previously cleared in k160156. The Blood Glucose Monitor, Test Strip, and Control Solutions are identical. The only difference between the predicate and proposed device is the labeling:

1) The accuracy information has been added to the modified StatStrip Xpress Blood Glucose Monitoring System kit carton label. This format is supported by the results of the newly conducted StatStrip Xpress Blood Glucose Monitoring System Human Factors Study.

2) The Accuracy table on the original StatStrip Xpress Glucose Test Strips Insert Sheet has been replaced by the Accuracy Table suggested in the FDA guidance document "Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use" (October 11, 2016).

3) The StatStrip Xpress Blood Glucose Monitoring System kit carton label has been updated with the following statement, "Proven hospital technology now available for personal use". This is supported in K160156 that the StatStrip Xpress Blood Glucose Monitoring System is equivalent to the Reference Device in K160156; StatStrip Xpress Glucose Hospital Meter System (K150461).

4) The statement of Interferences on the StatStrip Xpress Blood Glucose Monitoring System kit carton label has been updated to "No Known interferences from common medicines like Ibuprofen, Acetaminophen, and Vitamin C".

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, and StatStrip Xpress Glucose Test Strips. .

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

Summary of the Technological Characteristics:

The modified StatStrip Xpress Blood Glucose Monitor System that is the subject of this submission is identical in form, fit and function, to the device cleared in K160156. The StatStrip Xpress Glucose Monitoring System is intended for in vitro diagnostic use by lay people for the quantitative determination of glucose in whole blood.

The StatStrip Xpress Glucose Monitor is a hand-held testing device that works in conjunction with the StatStrip 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 patient test records. The user can recall and review test results.

A single coin battery powers the device, and is 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 Xpress Glucose Test Strips of this submission are identical in form, fit, function and packaging, to the glucose test strips originally cleared in K160156. 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 the amount of Glucose in the blood.

The StatStrip Xpress 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.

The Test Strip is designed such that when a drop of blood touched 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 available in cartons of 100 strips (50 strips/vial).

- 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: The StatStrip Xpress 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 Monitors.

- 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.

Table 1: Comparison of Predicate and Proposed devices

Characteristic	Predicate Device (K160156)	Proposed Device (K170464)
	StatStrip Xpress Blood Glucose Monitoring System	StatStrip Xpress Blood Glucose Monitoring System
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 (Level 1, 2, and 3). • The StatStrip Xpress Blood Glucose Monitoring System is intended for use outside the body (*in vitro* diagnostic 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 and StatStrip Xpress Glucose Test Strips. • The StatStrip Xpress Blood Glucose Monitoring System is intended for use outside the body (*in vitro* diagnostic use).

Characteristic	Predicate Device (K160156)	Proposed Device (K170464)
	StatStrip Xpress Blood Glucose Monitoring System	StatStrip Xpress Blood Glucose Monitoring System
Enzyme	Glucose Oxidase	Same
Operating Principle	Electrochemical biosensor, amperometric	Same
Sample type	Capillary whole blood (finger stick)	Same
Sample size	1.2 µL	Same
Sample application	Test Strip capillary draw	Same
Measuring range	20-600 mg/dL	Same
Hematocrit range	20-65%	Same
Reported output	mg/dL	Same
Time to Result	~ 6 seconds	Same
Quality control	3 levels	Same
Handheld	Yes	Same
Calibration	Automatic, no calibration code	Same
Data storage	400 test results	Same
Barcode	No	Same

Characteristic	Predicate Device (K160156)	Proposed Device (K170464)
	StatStrip Xpress Blood Glucose Monitoring System	StatStrip Xpress Blood Glucose Monitoring System
Power source	3v DC Li coin cell battery	Same
Dimensions	3.6x2.3x0.9 in (91.4x58.4x22.9 mm)	Same
Weight	2.65 ounces (75grams)	same

Summary of Testing:

Human Factors Study

A Human Factors study of 100 Intended Use Population (Type 1 and Type 2 Layperson Diabetics) was conducted to assess the overall understanding of the accuracy information presented on the proposed outer carton label of the StatStrip Xpress Blood Glucose Monitoring System.

Inclusion Criteria:

1. Is 18 years of age or older
2. Is able to read and write English
3. Has been diagnosed with Type 1 Diabetes or,
4. Has been diagnosed with Type 2 Diabetes or,

Exclusion Criteria:

1. Does not meet the inclusion criteria or,
2. Has a cognitive disorder or other condition, which, in the opinion of the investigator, would seriously compromise the integrity of the study.

Subject Demographics:

Table 1: Subject Age

Age	Number of Subjects
25-30	2
31-40	10
41-50	10
51-60	24
61-70	32
71-80	20
81-83	2
Total	100

Table 2: Subject Gender

Gender	Number of Subjects
Male	37
Female	63
Total	100

Table 3: Subject Race

Race	Number of Subjects
African American	54
Caucasian	45
Native American	1
Total	100

Table 4: Subject Education

Education (Total number of years)	Number of Subjects
8	2
9	2
10	2
11	2
12	75
13	3
14	11
15	0
16	3
Total	100

Methods and Procedures:

1. Potential Subjects were pre-screened by the study staff for inclusion into the study using the "Inclusion/Exclusion Form" (Form I/E).
2. The Subject completed the Informed Consent (IC) process.
3. Each Subject was assigned a Subject number by the study staff.
4. A study staff member gave the Subject the "Mathematics Understanding Assessment Form" (Form MUA) and asked them to answer the questions.
5. A study staff member provided the Subject with the Kit Carton label proposal for the StatStrip Xpress Blood Glucose Monitoring System.
6. Each Subject was then asked to completely review the Kit Carton label contents of the StatStrip Xpress Blood Glucose Monitoring System.
7. The Subject answered each of the questions on the forms to determine their level of understanding of the StatStrip Xpress Blood Glucose Monitoring System Kit Carton labels.
8. A study staff member provided the Subject with the Kit Carton label for the StatStrip Xpress Blood Glucose Monitoring System alongside draft Kit Carton label for the Nova Max Plus Blood Glucose Monitoring System.
9. Each Subject was asked to completely review and compare the labeling contents.

10. The Subject answered each of the questions to determine their ability to correctly interpret the accuracy information when comparing one meter's accuracy information to another meter's accuracy information.
11. The Subject answered each of the questions to determine how valuable the Kit Carton accuracy labeling information presented would be to them.

Study Findings:

Mathematics Assessment:
The average Subject score for the 10-question Mathematics Assessment was **71.3%** across all races, educational levels, ages, and both genders.

Human Factors Assessment:
The data collected during this Human Factors Study shows that Subjects with minimal education and who demonstrated limited mathematics skills in the mathematics assessment are able to understand the accuracy information presented on the proposed Nova StatStrip Xpress kit packaging.

Although the Subjects exhibited an average mathematical assessment score of 71.3% when performing basic mathematical percentage calculations, the Subjects exhibited a better than average (82.2% - 93.3%) ability to understand the accuracy information proposed for the device's outer kit carton.

Table 5: Summary of Responses to Objective Questions

Topic	Form Number	Average Score (%)
Mathematics Assessment	MUA	71.3
Understanding Front Kit Carton	HFA 1A (Questions 1-3)	93.3
Understanding Side Kit Carton	HFA 1B	82.2
Understanding of Accuracy Comparison Information System A vs. B	HFA 2	86.0
Understanding of Comparison Information System A vs. C	HFA 3	92.1
Understanding Comparison Information System A vs. D	HFA 4	91.7

The Subjects answers to the subjective questions indicated that an overwhelming majority understood the importance of accuracy when choosing a glucose meter to monitor their diabetes.

Furthermore, the Subjects understood the information presented to them on the proposed kit packaging, and believed that there is value in accuracy ratings when selecting a Blood Glucose Monitoring System.

Conclusion:

The proposed Accuracy Summary Chart and Accuracy Grade depictions evaluated in this study are an effective way to present the performance of the Nova StatStrip Xpress Blood Glucose Monitoring System to layperson Subjects and meets the predetermined acceptance criteria.