**K510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION**
**DECISION SUMMARY**
**ASSAY ONLY TEMPLATE**

**A. 510(k) Number:**

k170464

**B. Purpose for Submission:**

This submission seeks changes in labeling for the previously cleared StatStrip Xpress Blood Glucose Monitoring System (k160156). Accuracy information has been added to the outer carton labeling, and the presentation format of accuracy information on the test strip package insert has been modified.

**C. Measurand:**

Fresh capillary whole blood glucose from the fingertip

**D. Type of Test:**

Quantitative, amperometric assay (Glucose Oxidase)

**E. Applicant:**

Nova Biomedical Corporation

**F. Proprietary and Established Names:**

StatStrip Xpress Blood Glucose Monitoring System

**G. Regulatory Information:**

1. Regulation section:

   21 CFR 862.1345, Glucose test system

2. Classification:

   Class II

3. Product code:

   NBW, System, Test, Blood Glucose, Over The Counter

4. Panel:

   Clinical Chemistry (75)

## H. Intended Use:

1. Intended use(s):

   See indication(s) for use below.

2. Indication(s) for 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).

3. Special conditions for use statement(s):

   - For over-the-counter use
   - For single-patient use only.
   - Critically ill patients should not be tested with this device.
   - Inaccurate results may occur in severely hypotensive individuals or patients in shock.
   - Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
   - Incorrect result may occur in individuals who are dehydrated.
   - The system should not be used to test neonates.
   - Do not reuse; each Test Strip is for single use only.
   - Do not test samples other than fresh capillary whole blood obtained from the fingertip.
   - Do not use at altitudes above 15,000 feet (4572 meters) above sea level.
   - Do not use when humidity is higher than 90% and lower than 10%, as extremes in humidity may affect results.
   - Do not use when Hematocrit is outside the acceptable Hematocrit range for testing of 20% to 65%.
   - Not intended for the diagnosis or screening of diabetes.
   - This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as

part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodblorne pathogens.

4. Special instrument requirements:

StatStrip Xpress Blood Glucose Monitor

## I. Device Description:

The modified StatStrip Xpress Blood Glucose Monitoring System, which includes StatStrip Xpress Blood Glucose Monitor, StatStrip Xpress Glucose Test Strips, and StatStrip Xpress Glucose Control Solutions (Levels 1, 2, and 3, sold separately), is identical to the device cleared in k160156. Only labeling changes have been made to the outer box labeling and test strips package insert.

## J. Substantial Equivalence Information:

1. Predicate device name(s):

StatStrip Xpress Blood Glucose Monitoring System

2. Predicate 510(k) number(s):

k160156

3. Comparison with predicate:

| Similarities | | |
|---|---|---|
| Item | Candidate Device | Predicate Device (k160156) |
| Intended Use/Indications for Use | Intended to be used for the quantitative measurement of glucose in fresh capillary whole blood as an aid to monitor the effectiveness of diabetes control in people with diabetes. | Same |
| Specimen type | Fresh capillary whole blood from fingertip | Same |
| Test Principle | Electrochemical biosensor, amperometric | Same |
| Enzyme | Glucose Oxidase | Same |

| Differences | | |
|---|---|---|
| Item | Candidate Device | Predicate Device (k160156) |
| Outer carton labeling | System accuracy data and interference information included on the outer carton labeling | System accuracy data and interference information not included on the outer carton labeling |
| Test strip package insert | System accuracy data represented in one table for all glucose concentrations where data is separated into 'within 5%', 'within 10%', 'within 15%', and 'within 20%' bins. | System accuracy data represented in two tables for glucose concentrations < 75 mg/dL and ≥ 75 mg/dL where data is separated into 'within 5mg/dL', 'within 10 mg/dL', and 'within 15 mg/dL' bins for glucose concentrations < 75 mg/dL and data is separated into 'within 5%', 'within 10%', 'within 15%', and 'within 20%' bins for glucose concentrations ≥ 75 mg/dL. |

**K. Standard/Guidance Document Referenced (if applicable):**

No applicable standard was cited.

**L. Test Principle:**

The StatStrip Xpress Blood Glucose Monitoring System measures glucose levels using disposable test strips and a handheld meter. The test strip contains a flow channel to draw blood by capillary action into a biosensor measurement zone. The sensor comprises an enzyme (Glucose oxidase) that oxidizes glucose present in the blood sample. The sensor also contains an electron shuttle to re-generate, by oxidation, the active form of the enzyme. The meter applies a low electrical voltage to the sensor electrodes and measures a change in current caused by the electrochemical oxidation of the electron shuttle.

**M. Performance Characteristics (if/when applicable):**

This submission seeks changes in labeling for the previously cleared StatStrip Xpress Blood Glucose Monitoring System (k160156). The technological characteristics of the modified device are identical to the technological characteristics of the cleared device (k160156). The StatStrip Xpress Blood Glucose Monitoring System cleared in k160156 uses identical technology to the StatStrip Glucose Hospital Meter System (originally cleared in k060345 and modified in k063821, k070960, k132121, and k150461). Performance of the modified device was established using these previously cleared devices, which are cited (as

appropriate) in each section.

1. Analytical performance:

   *a. Precision/Reproducibility:*

   Within-run and intermediate precision were established in k060345.

   *b. Linearity/assay reportable range:*

   Linearity and reportable range were established in k060345.

   The reportable range for the StatStrip Xpress Blood Glucose Monitoring System is 20 to 600 mg/dL.

   Readings outside of reportable range
   Bench studies and software verification studies were provided to demonstrate that if a glucose measurement is less than 20 mg/dL, the result is flagged and a 'LO' indicator is displayed. If a glucose measurement exceeds 600 mg/dL, the result is flagged and a 'HI' indicator is displayed.

   *c. Traceability, Stability, Expected values (controls, calibrators, or methods):*

   Traceability
   The StatStrip Xpress Blood Glucose Monitoring System is traceable to NIST Standard SRM917B.

   Test Strip Stability
   Stability protocols and acceptance criteria for the StatStrip Xpress Blood Glucose Test Strips were evaluated in k060345 and found to be acceptable. The claimed closed-vial stability is 24 months at 34-86°F and 10-90% RH. The claimed open-vial stability is 6 months when stored at the recommended storage temperatures 34-86°F and 10-90% RH or until the expiration date printed on the label, whichever comes first.

   *d. Detection limit:*

   See the linearity study in Section M.1.b. above.

   *e. Analytical specificity:*

   Potential interference from some common endogenous and exogenous substances was established in k132121.

   The following information has been added to the outer carton labeling: "Eliminates interferences from common medicines such as Ibuprofen, Acetaminophen, and Vitamin C."

*f. Assay cut-off:*

Not applicable.

2. Comparison studies:

*a. Method comparison with predicate device:*

Method comparison studies were established in k060345.

*b. Matrix comparison:*

Not applicable. Capillary whole blood is the only indicated matrix.

3. Clinical studies:

*a. Clinical Sensitivity:*

Not applicable.

*b. Clinical specificity:*

Not applicable.

*c. Other clinical supportive data (when a. and b. are not applicable):*

Accuracy in the hands of the intended users was established in k160156.

Human factors study

Prior to conducting a human factors study to assess intended user understanding of accuracy labeling, the sponsor assessed ways to display device accuracy information on the outer box labeling of the device for easy understanding by the intended user. Twenty design concepts for accuracy labeling were created and assessed internally by the sponsor as well as through studies with external lay people with diabetes (who did not participate in the human factors study) to identify the most simple and easy to understand the information presented. These designs included varied displays such as text only, pie charts, bar charts, line graphs, and bulls eye graphs with and without text. Independent diabetes educator professionals were also consulted on the design and presentation of labeling. The results of this accuracy labeling design assessment supported the bulls eye graphic presented as part of this effort as easiest for lay users to understand.

A human factors study was then performed using the accuracy labeling design selected in the initial accuracy design phase assessment. For the human factors study, 100 male and female intended use subjects across ethnicities (African American,

Caucasian, Native American) and ages (25 to 83 years), and having not received higher levels of formal education (at least 75% of subjects completed 12 years or fewer of high school education; no more than 25% of subjects attended college or higher education) participated in the human factors study. Subjects were included in the study if they were 18 years of age or older, able to read and write English, diagnosed with Type 1 or Type 2 Diabetes, and met the educational requirements above. Subjects with a cognitive disorders or other similar conditions were excluded.

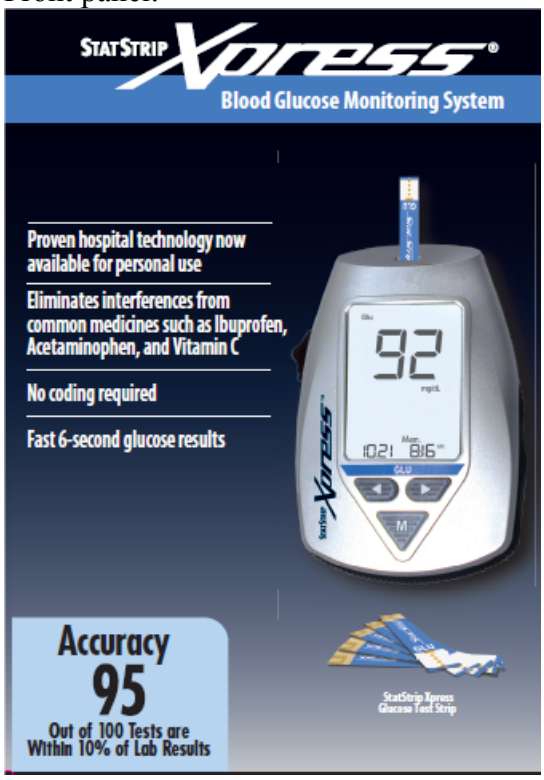
As part of the study, each subject completed a mathematics understanding assessment (MUA) in order to determine a subject's understanding of basic mathematics concepts. The MUA established the baseline numeracy skills (e.g., comparisons of two numbers, understanding of percentages) of the subjects since the human factors assessment of accuracy labeling comprehension incorporated basic mathematics concepts (e.g., comparisons of pairs of accuracy values). The average score for 100 subjects for the MUA was 71.3%.

As part of the assessment of accuracy labeling comprehension, each subject completed assessments for the front panel (1A) and side panel (1B) of the proposed outer carton labeling (System A) and comparisons of labeling for System A to System B (2), System C (3), and System D (4) to determine a subject's overall understanding of meter accuracy information.

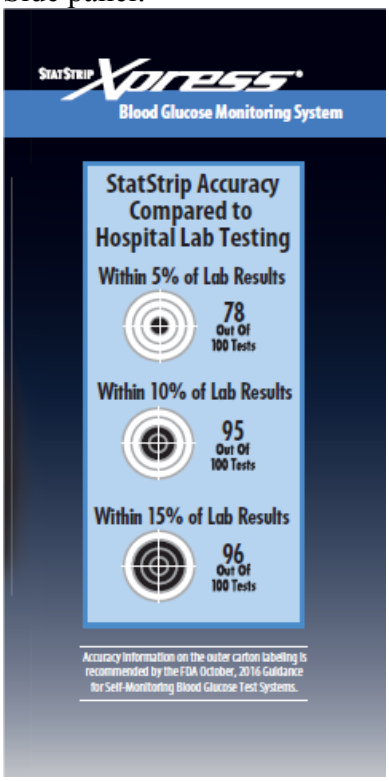
For assessment 1A and 1B, subjects were asked multiple choice questions about the front and side panels of the proposed labeling (System A). The front and side panels of the proposed labeling and the results of these assessments are shown below.

System A (proposed labeling)

Front panel:




Side panel:




Assessment 1A: Front panel of proposed labeling

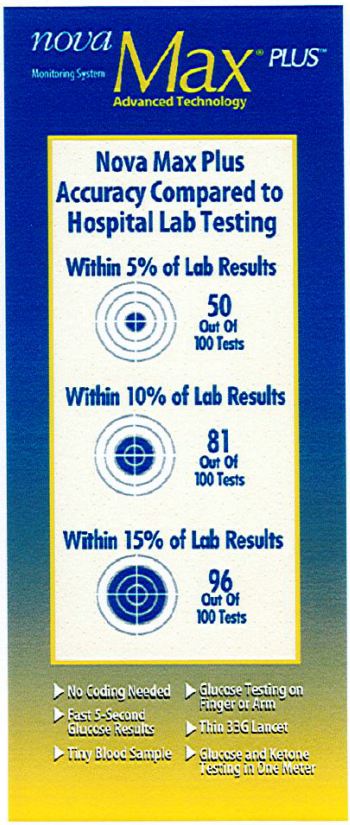
| Question | Average score for 100 subjects (%) |
|---|---|
| What is the Accuracy [within 10% of lab results] for this meter? | 92 |
| Is the Accuracy of 95 better than an Accuracy of 78? | 91 |
| An Accuracy of 95 is equal to which of the following? | 97 |

Assessment 1B: Side panel of proposed labeling

| Question | Average score for 100 subjects (%) |
|---|---|
| Out of 100 tests performed, how many glucose results are within 15% of a glucose test performed in a hospital lab? | 76 |
| True or False: 78 out of 100 tests performed on this meter are within 5% of glucose testing performed in a hospital lab? | 88 |
| Out of 100 tests performed, how many glucose results are within 10% of a glucose test performed within a hospital lab? | 89 |
| According to this table, 95 out of 100 tests are within 10% of lab results. Are the other 5 tests within 10% of lab results? | 52 |
| This labeling information compares the accuracy of this glucose meter to which of the following? (Select one) | 91 |

For assessments 2, 3, and 4, subjects were asked to compare the proposed labeling for System A to Systems B, C, or D. The side panels for Systems B, C, and D and the results of these assessments are shown below. The front panels for Systems B, C, and D (not shown) display the accuracy values within 10% of lab results (i.e., 81 out of 100 tests for System B, 89 out of 100 tests for System C, and 91 out of 100 tests for System D).

System B:




System C:


System D:

Assessments 2, 3, 4: Comparison of System A to Systems B, C, or D

| | Average score for 100 subjects (%) | | |
|---|---|---|---|
| Question | (2) System A vs. System B | (3) System A vs. System C | (4) System A vs. System D |
| Which meter has a [**higher or lower**] Accuracy [within 10% of lab results]? If unsure, please explain. | 98 | 97 | 98 |
| When comparing the two meters for results that are within **5%** of lab results, which meter is **more** accurate? If unsure, please explain. | 91 | 96 | 89 |
| When comparing the two meters for results that are within **10%** of lab results, which meter is [**less or more**] accurate? If unsure, please explain. | 87 | 93 | 89 |
| When comparing the two meters for results that are within **15%** of lab results, which meter is [**less or more**] accurate? If unsure, please explain. | 71 | 84 | 96 |
| Overall, which meter is [**less or more**] accurate? If unsure, please explain. | 89 | 90 | 94 |
| (Check True or False) For **System A**, there are more results that fall within **10%** of Lab Results than results that fall within **5%** of lab results? | 91 | 93 | 93 |
| (Check True or False) For **System [B or C or D]**, there are more results that fall within **5%** of Lab Results than results that fall within **10%** of lab results? | 75 | 84 | 83 |

The results for assessments 1A, 1B, 2, 3, and 4 shown above support the intended user understanding of the proposed outer carton accuracy labeling.

4. Clinical cut-off**:**

Not applicable.

5. Expected values/Reference range:

The StatStrip Xpress Blood Glucose Test Strips package insert includes the following:

> The normal fasting adult blood Glucose range for a person without diabetes is less than 100 mg/dL. One to two hours after meals, normal blood Glucose levels should be less than 140 mg/dL.

From: American Diabetes Association, Standards of Medical Care in Diabetes. Diabetes Care, Vol 40, Supplement 1. January 2017.

## P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Refer to the decision memorandum for k160156 for information related to hematocrit range, altitude, temperature and humidity, sample volume, infection control, electromagnetic compatibility, readability evaluation, and customer service.

## Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

## R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.