CLIA Waiver by Application
Approval Determination Decision Summary

A. Document Number

CW180005

B. Parent Document Number

k181043

C. Purpose of the Submission

This submission is a Dual 510(k) and CLIA Waiver by Application (Dual Submission) tracked as k181043 and CW180005. This CLIA Waiver Application is to expand CLIA waiver for the StatStrip Glucose Hospital Meter System to add capillary blood in all hospitalized patients.

D. Sample Type

Capillary fingertip whole blood

E. Type of Test or Tests Performed

Quantitative, test strip based measurement of blood glucose

F. Applicant

Nova Biomedical Corporation

G. Proprietary and Established Names

StatStrip Glucose Hospital Meter System

H. Test System Description

The StatStrip Glucose Hospital Meter is a hand-held testing device that works in conjunction with Nova StatStrip Glucose Hospital Meter Test Strips to measure glucose in a whole blood sample. Meter operation is self-prompting using an illuminated touch-screen Graphical User Interface (GUI). In addition to measuring glucose, the meter also stores patient test data, quality control test data and other information relating to the patient, patient sample, operator, reagents and meter. The test strips contain a reaction layer that contains a glucose-enzyme (greater than 1.0 IU) and ferricyanide as a mediator. The test strip is touched to a drop of blood to initiate the test process. 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.

This device was previously cleared (k060345 and k063821) and CLIA waived (k060345/A001) for use with capillary fingerstick whole blood, venous whole blood, arterial whole blood, neonatal heel stick and neonatal arterial whole blood samples. The indications for use were expanded and CLIA waiver granted (k132121) to include use of venous, arterial and neonatal blood samples in all hospitalized patients with a limitation against the use of capillary whole blood fingerstick samples in patients receiving intensive medical intervention/therapy. The current submission is to expand CLIA waiver to add the use of capillary fingerstick whole blood samples in all hospitalized patients including those receiving intensive medical interventions/therapy.

Three levels of control solutions (Level 1, Level 2, Level 3) and five levels of linearity solutions (Level 1, Level 2, Level 3, Level 4, Level 5) are available, separately, for use with the system for users to verify the performance of the system.

I. Demonstrating "Simple"

- The StatStrip Glucose Hospital Meter System consists of the fully automated StatStrip Glucose Hospital Meter and single-use Nova StatStrip Glucose Hospital Meter Test Strips.

- The StatStrip Glucose Hospital Meter System uses direct, unprocessed whole blood samples and requires no specimen manipulation before performing the test.

- Reagents are secured within the test strip. The meter shows graphically a step-by-step procedure how to run a glucose test. Once the test strip is inserted into the meter the sample is applied directly to the test strip and the test result is displayed. There are no further procedural steps.

- The StatStrip Glucose Hospital Meter System requires no operator intervention during the analysis steps.

- The StatStrip Glucose Hospital Meter System requires no technical or specialized training with respect to troubleshooting or interpretation of multiple or complex error codes. Error messages are unambiguous, and include easy-to-interpret solutions.

- The StatStrip Glucose Hospital Meter System requires no electronic or mechanical maintenance. Maintenance consists of general external cleaning and disinfection of the instrument.

- The StatStrip Glucose Hospital Meter System includes a quick start guide (QSG) with troubleshooting and simple error code descriptions.

J. Demonstrating "Insignificant Risk of an Erroneous Result"- Failure Alerts and Fail-safe Mechanisms

1. Risk Assessment

   CLIA waived status for the StatStrip Glucose Hospital Meter System was previously demonstrated in k060345/A001 and k132121.

2. Fail-Safe and Failure Alert Mechanisms

   a. Failure alerts (error messages) and fail-safe mechanisms (lockout functions)

      The system will provide an error message, or a lockout function will occur and will not allow output of test results for the following conditions:
      - If the battery is low a 'battery low icon' will be displayed.
      - Temperature Error – will be displayed if the environment is outside 59°F to 104°F (15°C to 40°C)
      - Analysis Cancelled, Bad Sample and Replace Strip errors – will be displayed and the user instructed to rerun the test with a new test strip.
      - Flow Error – displayed when the specimen is incorrectly drawn into the test strip due to insufficient volume or incorrect sample application.
      - 'Hi' is displayed when the glucose result is greater than 600 mg/dL.
      - 'Lo' is displayed when the glucose result is less than 10 mg/dL.

   b. External control material:
      i. The use of external quality control material is recommended to demonstrate that the StatStrip Glucose Hospital Meter and test strips are working properly. The labeling states that user should perform quality control testing only with the StatStrip Glucose Control Solutions.

      ii. The frequency of running quality controls is stated in the labeling.

         It is recommended that two different levels of StatStrip Glucose Control Solutions be run each 24 hours of testing prior to testing of patient specimens and during the following circumstances:
         - Each new operator
         - Before using the meter for the first time
         - If a patient test has been repeated and the blood glucose results are still lower or higher than expected
         - If there are other indications that the system is not working properly
         - Whenever problems (storage, operator, instrument) are identified or anytime there is a concern the accuracy of the meter may have been affected by rough handling (such as dropping the meter).
         - As required by the institution's quality control policy or local regulatory requirements

ii. Directions for use are clearly stated in the labeling (QSG, user manual and test strip insert).

iii. Storage and stability are stated in labeling. The user should follow the manufacture's instructions for storage and stability.

iv. Number of levels; 3 levels (Level 1, Level 2, Level 3)

b. Flex Studies and Studies for Fail-Safe and Failure Alert Mechanisms

Flex studies were previously demonstrated in k060345/A001.

K. Demonstrating "Insignificant Risk of an Erroneous Result" (Accuracy)

1. Clinical Study Design

Method comparison studies were conducted using capillary fingerstick samples obtained at three hospital sites as follows:

Study 1

For Study 1, 568 capillary whole blood fingerstick specimens were obtained from patients within three different critical care units including the cardiovascular intensive care unit (CVICU), medical intensive care unit (MICU), and the operating room (OR). This study included 80 unique patient conditions receiving a total of 3,785 medications representing 17 parent drug classes. All testing with the StatStrip Blood Glucose Hospital Meter (StatStrip Meter) was performed by CLIA waived operators (non-laboratory personnel, typically nursing staff) within each of these three critical care settings. Capillary whole blood glucose results on the StatStrip Meter were compared to matched arterial or venous plasma results obtained on a comparator method, the Roche Cobas Modular P800 Hexokinase System, located in a central laboratory. The glucose ranges of the samples, according to the comparator method, ranged from 74 mg/dL to 379 mg/dL glucose. The results from the capillary fingerstick samples obtained from the StatStrip Hospital Meter compared to the results from the comparator method are summarized below:

Fingertip capillary samples with glucose concentrations <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 12 mg/dL	Within ± 15 mg/dL	Exceeds ± 15 mg/dL
1/1 (100%)	1/1 (100%)	1/1 (100%)	1/1 (100%)	0/1 (0%)

Fingertip capillary samples with glucose concentration ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 12 %	Within ± 15 %	Within ± 20 %	Exceeds ± 20 %
277/567 (48.9%)	450/567 (79.4%)	484/567 (85.4%)	516/567 (91.0%)	549/567 (96.8%)	18/567 (3.2%)

Study 2
Across two different medical centers, over 16,000 paired critical care capillary glucose specimens were retrospectively identified and met the following criteria:

Within critical care departments, a capillary fingerstick specimen, and a venous/arterial glucose result were measured at the bedside by a CLIA Waived operator using the BGMS.

Subsequently a plasma glucose test was performed on the same subject on the central laboratory hexokinase method within 15 minutes.

Capillary whole blood glucose results on the StatStrip Meter were compared to matched arterial or venous plasma results obtained on a comparator method, Roche Cobas Modular P800 Hexokinase System. The glucose ranges of the samples, according to the comparator method, ranged from 27 mg/dL to 667 mg/dL glucose. The results from the capillary fingerstick samples obtained from the StatStrip Hospital Meter compared with the results from the comparator method are summarized below:

Fingertip capillary samples with glucose concentrations <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 12 mg/dL	Within ± 15 mg/dL	Exceeds ± 15 mg/dL
907/1894 (47.9%)	1470/1894 (77.6%)	1614/1894 (85.2%)	1737/1894 (91.7%)	157/1894 (8.3%)

Fingertip capillary samples with glucose concentration ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 12 %	Within ± 15 %	Within ± 20 %	Exceeds ± 20 %
7473/14884 (50.2%)	11087/14884 (74.5%)	12799/14884 (86.0%)	13712/14884 (92.1%)	14350/14884 (96.4%)	534/14884 (3.6%)

2. Comparative Method (CM)

Cobas Modular P800 hexokinase System from Roche Diagnostics, Indianapolis, IN.

3. FDA Panel Meeting March 30th, 2018

A meeting of the Clinical Chemistry and Clinical Toxicology panel was held on March 30th, 2018, to discuss the risk and benefits of using capillary fingerstick blood samples from all hospital patients, including patients receiving intensive medical intervention/therapy. The panel was presented data from 3 studies using two different blood glucose meters. Two of the studies presented to the panel were the studies described above performed by Nova Biomedical using the StatStrip Glucose Hospital Meter System. The panel deliberated on the following question:

"Given the data presented, what are the relevant factors FDA should weigh in considering whether capillary blood glucose meter testing in intensively treated population would meet the criteria for CLIA waiver (i.e., "simple" and with "an insignificant risk of an erroneous result")?"

The panel discussed that there is a difference in performance between venous/arterial specimens and capillary blood specimens with regard to glucose meter accuracy in patients receiving intensive medical intervention/therapy that is not present in less sick/fragile patients. However, this difference did not appear to be related to user technique or meter technology, but rather appears to be biological in nature. The panel stressed the need for labeling to identify this limitation and to caution users to be aware that capillary blood may not always be the appropriate specimen type. The panel also stressed the need for good quality management programs within critical care units.

Given these mitigations, the panel consensus was that devices with capillary performance data in this patient population that is similar to that presented at the panel meeting should be considered suitable for waiver.

We have considered the data presented by Nova Biomedical using the StatStrip Glucose Hospital Meter System in capillary specimens in patients receiving intensive medical intervention/therapy, the clinical use scenarios for this device within hospitals, and the recommendations of the Clinical Chemistry and Clinical Toxicology Advisory Panel, and we have determined that these data support a CLIA waiver approval decision for the StatStrip Glucose Hospital Meter System.

L. Labeling for Waived Devices

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

- The Quick Reference Guide and User's Manual are written at no higher than a 7th grade reading level.

- The User's Manual and Quick Reference Guide identify the test as CLIA waived.

- The User's Manual and test cartridge package insert contain a statement that a Certificate of Waiver is required to perform the test in a waived setting.

- The User's Manual and Quick Reference Guide contain a statement that laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test. 42 CFR 493.15(e)(1).

- The User's Manual and Quick Reference Guide provide instructions for conducting quality control procedures.

M. Conclusion

The submitted information in this CLIA waiver application is complete and supports a CLIA waiver approval decision.