CLIA Waiver by Application
Approval Determination Decision Summary

A. Document Number

CW180011

B. Parent Document Number

k182549

C. Purpose of the Submission

This submission is a Dual 510(k) and CLIA Waiver by Application (Dual Submission) tracked as k182549 and CW180011. This CLIA Waiver Application is to expand CLIA waiver for the StatStrip Xpress 2 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 Xpress 2 Glucose Hospital Meter System

H. Test System Description

The StatStrip Xpress 2 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. The test strips contain a reaction layer that contains a glucose-enzyme 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.

The StatStrip Xpress 2 Glucose Hospital Meter was cleared (k152986 and k163490) and CLIA waiver granted for use with 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 the CLIA waiver for the StatStrip Xpress 2 Glucose Hospital Meter to add the use of capillary fingerstick whole blood samples in all hospitalized patients including those receiving intensive medical interventions/therapy.

An earlier model of this device, the StatStrip Glucose Hospital Meter, 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 (k132121) and granted CLIA waiver granted 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 indications for the StatStrip Glucose Hospital Meter were further expanded (k181043) and CLIA waived (CW180005) to add the use of capillary fingerstick whole blood samples in all hospitalized patients including those receiving intensive medical interventions/therapy.

The StatStrip Xpress 2 Glucose Hospital Meter uses the exact same technology as the StatStrip Glucose Hospital Meter. Both meters use the Nova StatStrip Glucose Hospital Meter Test Strips to measure glucose, require the same volume of sample, have the same glucose measuring range, and have the same indications for use. The systems differ in minor user preference features that do not impact the usability of the device, such as size of the meter, data storage specifications, and power source. Both systems use 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) that are available, separately, for use with the system for users to verify the performance of the system.

I. Demonstrating “Simple”

- The StatStrip Xpress 2 Glucose Hospital Meter System consists of the fully automated StatStrip Xpress 2 Glucose Hospital Meter and single-use Nova StatStrip Glucose Hospital Meter Test Strips.

- The StatStrip Xpress 2 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. 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 Xpress 2 Glucose Hospital Meter System requires no operator intervention during the analysis steps.

- The StatStrip Xpress 2 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 Xpress 2 Glucose Hospital Meter System requires no electronic or mechanical maintenance. Maintenance consists of general external cleaning and disinfection of the instrument.

- The StatStrip Xpress 2 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 Xpress 2 Glucose Hospital Meter System was previously demonstrated in k150461.

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:
      - .
      - Operating Temperature Error (E-2) will be displayed if the environment is outside 41°F to 104°F (5°C to 40°C).
      - Used Strip Error (E-3) will be displayed when a test strip that was previously used is inserted into the meter.
      - Short Sample Error (E-4) will be displayed when insufficient sample is drawn into the test strip.
      - Bad Strip Error (E-8) will be displayed when the test strip is defective.
      - Bad Sample Error (E-9) will be displayed when a problem is detected with the sample.
      - '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 Xpress 2 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 manufacturer's instructions for storage and stability.

iv. Three levels of ready-to-use liquid control solutions are available for use (Level 1, Level 2, Level 3).

c. 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)

Method comparison studies were previously conducted in k181043 and CW180005. The clinical data obtained supports the expanded CLIA waiver to add capillary blood in all hospitalized patients to the StatStrip Xpress 2 Glucose Hospital Meter System.

L. Labeling for Waived Devices

- The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.
- The User's Manual and Quick Reference Guide identify the test as CLIA waived.
- The User's Manual and test strip 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.

- 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.