CLIA Waiver by Application Approval Determination

Decision Summary

A. Document Number

CW230017

B. Parent Document Number

K232075

C. CLIA Waiver Type:

Dual 510(k) and CLIA Waiver by Application (Dual Submission)

D. Applicant

Nova Biomedical Corporation

E. Proprietary and Established Names

StatStrip Glucose Hospital Meter System

F. Measurand (analyte)

Glucose oxidase

G. Sample Type(s)

Capillary whole blood (finger stick), venous whole blood, arterial whole blood, neonatal arterial whole blood samples, and neonatal heel stick.

H. Type of Test

Quantitative, amperometric assay

I. Test System Description

1. Overview

The StatStrip Glucose Hospital Meter System is based on electrochemical biosensor technology and the principle of capillary action. The system quantitatively measures blood glucose levels using glucose oxidase enzyme chemistry. The electrons generated during this reaction are transferred from the blood to the electrodes. The magnitude of the

resultant current is proportional to the concentration of glucose in the specimen and the signal is converted to a plasma equivalent result that is displayed on the meter. This device was previously cleared and CLIA waived in K181043 and CW180005.

The current submission focuses on changes made to the meter to include a change of the position of the test strip port, addition of wireless charging, minor changes to the user interface, increase in data storage capacity of operator records and the addition of a validated cleaning and disinfecting wipe .

To support that the modified device is simple and has an insignificant risk of an erroneous results, the sponsor performed a risk analysis and flex studies, validated the software, EMC, electrical safety, wireless, and cybersecurity elements associated with the use of the device, and performed a human factors study as described below.

2. Test System Components

The StatStrip Glucose Hospital Meter System consists of a hand held StatStrip Glucose Hospital meter with docking station, and StatStrip Glucose Test Strips (sold separately). The Nova StatStrip Control Solutions include Levels 1, 2 and 3.

J. Demonstrating "Simple"

- The meter does not require the user to input a test strip code or perform any other calibration. The change of the position of the test strip port did not impact the performance of the device.

- Contains a quick reference instruction sheet that is written at no higher than a 7th grade reading level. Labeling identifies the modifications to the device (i.e. a change of the position of the test strip port, addition of wireless charging, changes to the user interface, increase in data storage capacity of operator records and the addition of a validated cleaning and disinfecting wipe). Collectively, these modifications did not impact the performance of the device.
- The sponsor provided information in the form of supplemental and flex studies to demonstrate that the modification did not impact the simplicity of the device.

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

1. Risk Analysis

   A risk analysis was conducted to identify and evaluate hazards related to the modifications of the StatStrip Glucose Hospital Meter System. All risks of harm to the patient or operator were mitigated to an acceptable level, and were supported by software, EMC, electrical safety, wireless, and cybersecurity validation testing.

   a. The sponsor provided documentation certifying that acceptable electrical safety and electromagnetic compatibility (EMC) testing had been performed and the system was found to be compliant.

   b. The sponsor provided documentation certifying that acceptable software validation and cybersecurity testing had been performed and the system was found to be compliant.

2. Flex Studies

   Based on the risk analysis and the identification of potential errors, the following flex studies were conducted on the StatStrip Glucose Hospital Meter System to demonstrate that the test system is robust when its operational limits are stressed due to potential operator errors and factors affecting test system integrity. The studies were conducted using the StatStrip Glucose Hospital Meter and StatStrip Glucose Test Strips:

   a. A battery consumption and battery life study was performed to assess the number of tests that can be run under normal operating conditions without recharging and demonstrated that the rechargeable battery will last as long as the meter life (minimum of 3 years).

   b. A study was performed to confirm that there are no problems with the functionality of the StatStrip Glucose Hospital Meter following drop unit testing. The meter was dropped 10 times from a height of 60 inches such that each face of the item made impact with a hard surface (e.g. tile floor). All of the verification results were within the criteria limits and no deterioration in functionality was observed.

   c. To support the changes to the exterior of the meter and the additional claimed cleaning and disinfecting wipe, the sponsor conducted cleaning and disinfection studies with the modified meter. Disinfection efficacy studies were performed on the external meter materials by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with each of the chosen disinfectants separately, Clorox Germicidal Wipes (EPA registration # 67619-12) and Super Sani Disposable Wipes (EPA registration #9480-4). A robustness study was also conducted by the sponsor demonstrated that there was no change in performance or in the external materials of the meter after 10,950 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) using both of the wipes separately to simulate 3 years of multiple-patient device use. Labeling

was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

L. Demonstrating "Insignificant Risk of an Erroneous Result"-Accuracy

a. A usability study was conducted in which the changes to the device (e.g., relocation of the test strip port, use of a new bar code scanner, scroll functionality, etc.) were evaluated by CLIA waived users. The operators were given the meter, test strips, control solutions, user manual and the quick reference guide in order to perform the test. No other materials or instructions were provided, and the operators received no additional training to perform the test. Upon completion, each operator completed a questionnaire to evaluate the ease of using the candidate device. The participants were able to successfully perform the test, received accurate results, and found the StatStrip Glucose Hospital Meter System easy to use and the user manual and the quick reference guide easy to follow.

b. Supplemental precision and accuracy bench studies were performed, in which the results from venous whole blood samples obtained from the StatStrip Glucose Hospital Meter were compared to the results from the comparator method (YSI 2300 STAT Glucose and L-Lactate analyzer) and found to be acceptable.

M. Labeling for Waived Devices

The labeling consists of:

1. Quick Reference Guide for the Glucose Hospital Meter System

2. The StatStrip Glucose Hospital Meter Instructions for Use Manual

2. <u>The following elements are appropriately present:</u>

- The Quick Reference Guide 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 as per 42 CFR 493.15(e)(1).
- The User's Manual and Quick Reference Guide provide instructions for conducting quality control procedures.
- The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

N. Conclusion:

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