DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 26, 2017

NOVA BIOMEDICAL CORPORATION
PAUL MACDONALD
SENIOR DIRECTOR OF REGULATORY AFFAIRS
200 PROSPECT STREET
WALTHAM MA 02454

Re: K171059
Trade/Device Name: Nova StatSensor Creatinine Hospital Meter System
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: II
Product Code: CGL
Dated: April 26, 2017
Received: April 27, 2017

Dear Paul MacDonald:

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 Parts 801 and 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171059

Device Name
Nova StatSensor Creatinine Hospital Meter System

Indications for Use *(Describe)*

The Nova StatSensor Creatinine Hospital Meter System consists of the StatSensor Creatinine Hospital Meter and the Stat-Sensor Creatinine Test Strips. The Nova StatSensor Creatinine Hospital Meter System is intended for in vitro diagnostic use by healthcare professionals and for Point-Of-Care usage for the quantitative measurement of creatinine in capillary, venous, and arterial whole blood. Creatinine measurements are used in the diagnosis and treatment of renal diseases and in monitoring renal dialysis. Not for use in neonates.

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.

510(k) Summary

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: Adam Heroux
Date Prepared: **May 26, 2017**

Proprietary Name: Nova StatSensor Creatinine Hospital Meter System

Common or Usual Name: Electrode, Ion Based, Enzymatic, Creatinine

Device Classification:

Classification Names:	Class No.	Reg. No.	Class	Review Panel
Creatinine test system	CGL(75)	862.1225	II	Clinical Chemistry

Product Codes: CGL, Electrode, Ion Based, Enzymatic, Creatinine

Predicate Device: K070068 Nova StatSensor Creatinine Hospital Meter

Device Description:

The Nova StatSensor Creatinine Hospital Meter System consists of a hand held meter, test strips, control solutions, and linearity solutions. The Nova StatSensor Creatinine Hospital Meter System is a hand-held, battery-powered, *in vitro* diagnostic laboratory instrument that works in conjunction with Nova Biomedical creatinine electrochemical test strips to measure creatinine in a whole blood sample, a Quality Control (QC) solution, linearity, or proficiency solutions. In addition to measuring creatinine, the meter stores patient test data, QC test data, and other information relating to patient, patient sample, operator, reagents, and the meter. A user interface provides a self-prompting environment via a color LCD. The Charging Station recharges the batteries of the meter.

Mechanism of Action:

A test strip is inserted into the meter, and the sample is applied to the sample entry end of the strip. The test strip contains a reaction layer that contains creatinine amidohydrolase, creatinine amidinohydrolase and sarcosine oxidase that reacts with the test sample. When enough sample has been added to the test strip (sample is drawn into strip though capillary action) the meter begins its analysis. A digital readout is displayed on the meter in 30 seconds.

Test Strips:

The test strips contain a reaction layer that contains creatinine amidohydrolase, creatinine amidinohydrolase and sarcosine oxidase. The test strip is touched to a drop of blood to initiate the test process. The test strip is designed such that when a drop of blood is touched to the end of the test strip, the blood is drawn into the reaction space via capillary action. A simple one-step process provides a blood creatinine result. Test strips are sold in vials of 25 strips.

The Nova StatSensor Creatinine Test Strips that are intended for use with the StatSensor Creatinine Hospital Meter are identical in form, fit, function and packaging, to the Nova StatSensor Creatinine Test Strips previously cleared for use with the Nova StatSensor Creatinine Hospital Meter System (K070068).

No changes have been made to Nova StatSensor Creatinine Test Strips and they are not a subject of this submission.

Control and Linearity Solutions:

The control solutions contain aqueous assayed solutions, containing creatinine, preservative, viscosity-adjusting agent, and other non-reactive ingredients (dye). They contain no products of human origin. There are three levels of controls, (Level 1, Level 2 and Level 3). These solutions are offered for sale separately from the meter.

The linearity solutions contain creatinine, viscosity agent, preservatives and other non-reactive ingredients (dye). They contain no products of human origin. These solutions are offered to users to verify the performance of the system. There are five levels of linearity solutions (Level 1, Level 2, Level 3, Level 4, Level 5). These solutions are offered for sale separately from the meter.

The Nova StatSensor Creatinine Control and Linearity Solutions that are intended for use with the StatSensor Creatinine Hospital Meter are identical in formulation and packaging, to the Control and Linearity Solutions originally cleared for use with the Nova StatSensor Creatinine Hospital Meter System (K070068). No changes have been made to Nova StatSensor Creatinine Control and Linearity Solutions and they are not a subject of this submission.

Docking/Charging Station:

The meter charging station is a stationary accessory used to recharge the meter. The charging station has one slot for the meter to be placed for charging and a slot for an extra battery to be charged. The charging station should be located central to the patient care area being served by the meter (e.g. a nursing station). The data charging station must remain plugged in to a wall outlet for power. Replacement batteries are offered separately.

Intended Use:

The Nova StatSensor Creatinine Hospital Meter System consists of the StatSensor Creatinine Hospital Meter and the StatSensor Creatinine Test Strips. The Nova StatSensor Creatinine Hospital Meter System is intended for in vitro diagnostic use by healthcare professionals and for Point-Of-Care usage for the quantitative measurement of creatinine in capillary, venous, and arterial whole blood. Creatinine measurements are used in the diagnosis and treatment of renal diseases and in monitoring renal dialysis. Not for use in neonates.

Summary of the Technological Characteristics:

The Nova StatSensor Creatinine Hospital Meter System that is the subject of this submission uses the exact same technology, functionality, analytical and operational performance characteristics, as the predicate. The Main CPU and the Primary Strip Board Electronics are identical in both the meters. The only difference is the change in ergonomic design.

Table 1: Comparison of Predicate and Proposed Devices

Characteristic	Predicate: Nova StatSensor Creatinine Hospital Meter (K070068)	Proposed: Nova StatSensor Creatinine Hospital Meter
Intended Use	Is intended for in vitro diagnostic use by healthcare professionals and for Point- Of-Care usage for the quantitative measurement of creatinine in capillary, venous, and arterial whole blood. Creatinine measurements are used in the diagnosis and treatment of renal diseases and in monitoring renal dialysis. Not for use in neonates.	Same as Predicate
Measuring Range	0.30 - 12.0 mg/dL or 27-1056 µmol/L	Same as Predicate
Acceptable Samples	Whole blood: Capillary, Arterial,Venous	Same as Predicate
Measuring Technology	Enzyme, Amperometric	Same as Predicate
Operating Principle	Electrochemical biosensor test strip	Same as Predicate
Analysis Time	30 seconds	Same as Predicate
Sample Volume	1.2 µL	Same as Predicate
Sample application	Test strip capillary draw	Same as Predicate
Handheld meter	YES	Same as Predicate
Meter Calibration	Automatic, no Calibration Code	Same as Predicate
Docking/Charging Station	Desk mount	Same as Predicate
Meter Memory	1000 patient tests, 200 QC tests, 4000 Operators	Same as Predicate
Power source	3.7V Li Polymer battery (Rechargeable/Replaceable)	Same as predicate
Controls:	Liquid, 3 levels	Same as Predicate
Linearity Solutions	Liquid, 5 levels	Same as Predicate
Test Strips – Active reagent:	creatinine amidohydrolase, creatine amidinohydrolase and sarcosine oxidase	Same as predicate
Screen Display	Small Font Size	Large Font Size
Keypad	Hard buttons	Soft Buttons
Dimensions	Height:153 mm (6.0 in) Width: 82.5 mm (3.25 in) Depth 46 mm (1.8 in)	Height: 146 mm (5.8 in) Width:79 mm (3.1 in) Depth:30 mm (1.18 in)
Weight	360 grams (0.8 lb)	220 g (0.49 lb)
Bar code scanner	Bottom of the Meter (1D: Symbol 965, 2D: Symbol SE4400, 2D: Symbol SE4500)	Top of the Meter (2D: Opticon MDI3100)
Housing Material	Aluminum	Lighter Plastic
Location of Strip Port	Top of Meter	Bottom of the Meter