January 21, 2026

Nova Biomedical Corporation
Mariya Cesnulevicius
Regulatory Affairs Manager
200 Prospect St.
Walham, MA 02454

Re: K251281
Trade/Device Name: Nova Max Creat eGFR Monitoring System
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Code: SHB
Dated: December 22, 2025
Received: December 22, 2025

Dear Mariya Cesnulevicius:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

PAULA V. CAPOSINO -S

Paula Caposino, Ph.D.
Deputy Director
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251281

Device Name
Nova Max Creat eGFR Monitoring System

Indications for Use *(Describe)*
The Nova Max Creat eGFR Monitoring System is comprised of the Nova Max Creat eGFR Monitor and the Nova Max Creat eGFR Test Strips.

The Nova Max Creat eGFR Monitoring System is intended for in vitro diagnostic use for the quantitative measurement of creatinine and estimation of glomerular filtration rate (eGFR) in fresh capillary whole blood obtained from the fingertip of adult patients aged 18 and above. The system is intended for single patient home use by prescription only and should not be shared. It is intended for use by patients as an aid to monitor kidney function on the order of a treating healthcare professional.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

510(k) Owner: Nova Biomedical Corporation

Establishment Registration Number: 1219029

510(k) Number: K251281

Address: 200 Prospect Street
Waltham, MA, 02454 USA

Phone: 781-894-0800

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Primary Contact Person

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Robert Zinck,
Director of Regulatory and Clinical Affairs

Date Prepared

January 21, 2026

Trade Name

Nova Max Creat eGFR Monitoring System

Common Name

Creatinine Test System

Classification Name

Classification Name	Product Code	Regulation Number	Classification	510(k) Review Panel
Creatinine test system	SHB	862.1225	Class II	Clinical Chemistry

Predicate Device

K171059, Nova StatSensor Creatinine Hospital Meter System

Device Description

The Nova Max Creat eGFR Monitoring System consists of Nova Max Create eGFR Monitor and Nova Max Create eGFR Creatinine-Test Strips. The Nova Max Creat eGFR test strips, Nova Max Creat eGFR control solution (Level 1 and Level 2), and a single-use, disposable, 21 gauge safety lancet can be purchased separately.

Nova Max Creat eGFR Monitor
The monitor is intended to be used in conjunction with the Nova Max Creat eGFR Creatinine-Test Strips to measure creatinine and calculate estimated glomerular filtration rate (eGFR) using capillary whole blood obtained from the fingertip. The hand-held monitor is lightweight, portable, utilizes a 2.8" color touchscreen display and has capability for storage (400 test samples and/or quality control samples) and review of data. The monitor is powered by a rechargeable, 3.7 V Li polymer battery.

Nova Max Creat eGFR Creatinine-Test Strips
The Nova Max Creat eGFR Creatinine-Test Strip is designed with an electrode that measures creatinine levels. Creatinine in the capillary whole blood sample mixes with the reagents in the test strip to produce an electric current. The amount of current that is produced depends on how much creatinine is in the sample. A digital readout is displayed on the monitor in 30 seconds, the eGFR is calculated using patient information and the measured creatinine level. The test strips are for single use only.

Nova Max Creat eGFR Creatinine Control Solutions
The Nova Max Creat eGFR Creatinine Control Solution is used as a quality control check to ensure that the Nova Max Creat eGFR Monitor and the Nova Max Creat eGFR Creatinine-Test Strips are working properly as a system. There are two levels of Nova Max Creat eGFR Creatinine Control Solution. Each level of control solution has a known creatinine concentration that reacts with the reagents in the test strip.

Indications for Use

The Nova Max Creat eGFR Monitoring System is comprised of the Nova Max Creat eGFR Monitor and the Nova Max Creat eGFR Test Strips.

The Nova Max Creat eGFR Monitoring System is intended for in vitro diagnostic use for the quantitative measurement of creatinine and estimation of glomerular filtration rate (eGFR) in fresh capillary whole blood obtained from the fingertip of adult patients aged 18 and above. The system is intended for single patient home use by prescription only and should not be shared. It is intended for use by patients as an aid to monitor kidney function on the order of a treating healthcare professional.

Summary of Performance Testing

Analytical bench and clinical testing were conducted to demonstrate that the Nova Max Creat eGFR Monitoring System achieves its intended purpose at the intended use setting.

Linearity Testing
Testing was performed to validate the Nova Max Creat eGFR Monitoring System linearity. Ten (10) specimens were tested on the Nova Max Creat eGFR Monitoring System. The same specimens were analyzed on the reference method. The results met the acceptance criteria, validating the linearity of the Nova Max Creat eGFR Monitoring System across the measurement range of 0.30 mg/dL to 7.00 mg/dL.

Analytical Specificity
The analytical specificity for the Nova Max Creat eGFR Monitoring System was assessed by testing the effect of various exogenous and endogenous substances on the measurement of creatinine by the system. Whole blood samples were spiked with forty-six (46) potential interferents and the creatinine concentration was measured with the Nova Max Creat eGFR Monitoring System.

The test substance was considered to be an interfering substance if the absolute difference between the test value and the control value was greater than 10% for creatinine concentration higher than 2 mg/dL, and greater than ± 0.2 mg/dL if the creatinine concentration is less than 2 mg/dL.

Based upon the results, all potential interfering substances tested met the acceptance criteria and were demonstrated not to have clinical interference. No clinical interference was identified up to the test concentrations reported in **Table 1**.

Table 1, Interference Test Result Summary

#	Interferent	Interference concentration	#	Interferent	Interference concentration
1	Acetaldehyde	0.2 mg/dL	24	Glucose	1000 mg/dL
2	Acetaminophen	15.6 mg/dL	25	High Hct and Low Hct	20 – 70 %
3	N-Acetyl-L-Cysteine	15 mg/dL	26	Ibuprofen	22 mg/dL
4	Ascorbic Acid	5.25 mg/dL	27	Paracetamol-4-acetamidopenol	30 mg/dL
5	β-Hydroxybutyric Acid	65 mg/dL	28	Pyruvate	5 mg/dL
6	Potassium bicarbonate	294 mg/dL	29	Lithium Salicylate	3 mg/dL
7	Bilirubin (unconjugated)	40 mg/dL	30	Potassium thiocyanate	6 mg/dL
8	Calcium Chloride	20 mg/dL	31	Urea	120 mg/dL
9	Creatine	5 mg/dL	32	Farxiga (dapagliflozin)	0.6 mg/dL
10	Dopamine Hydrochloride	2 mg/dL	33	Kerendia (finerenone)	1.2 mg/dL
11	Formaldehyde	0.4 mg/dL	34	Jardiance (empagliflozin)	1.5 mg/dL
12	Glycolic Acid	76 mg/dL	35	Lithium Heparin	1.2 mg/dL
13	Hydroxyurea	4 mg/dL	36	Lithium Bromide	325.69 mg/dL
14	Lithium Lactate	90 mg/dL	37	Hemoglobin	2600 mg/dL
15	Methyldopa	5 mg/dL	38	Cholesterol	1000 mg/dL
16	pH	8.0	39	L-Dopa	0.3 mg/dL
17	Sodium Thiosulfate	265 mg/dL	40	Maltose	360 mg/dL
18	Triglyceride	1500 mg/dL	41	Intralipid	2000 mg/dL
19	Uric Acid	23.5 mg/dL	42	Lactic Acid	108.1 mg/dL
20	Acetoacetate	20 mg/dL	43	Salicylic Acid	60 mg/dL
21	Acetylsalicylic Acid	3 mg/dL	44	Semaglutide (Ozempic or Wegovy)	0.144 mg/dL
22	Chlorpromazine HCl	0.4 mg/dL	45	Tirzepatide (Mounjaro)	0.9 mg/dL
23	Ethanol	600 mg/dL	46	Bilirubin (conjugated)	40 mg/dL

Limits of Detection and Quantification

Testing was conducted to assess the analytical sensitivity of the Nova Max Creat eGFR Monitoring System. Blank whole blood samples were tested to estimate the limit of the blank (LoB). This value was used to select a low level of creatinine concentration to determine the LoD and LoQ. Low level samples were prepared with creatinine concentration close to the estimated low value for creatinine concentration. These samples were tested repeatedly on the Nova Max Creat eGFR Monitoring System. Samples were also tested on the reference analyzer.

The study yielded the following results for creatinine:
Limit of Blank (LoB) = 0.078 mg/dL
Limit of Detection (LoD) = 0.174 mg/dL
Limit of Quantification (LoQ) = 0.174 mg/dL.

Traceability

Nova Max Creat eGFR Creatinine Control Materials are traceable to NIST Standard Reference Material 967b

Precision

Total Imprecision of the Nova Max Creat eGFR Monitoring System was assessed using methods described in CLSI "Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guidelines – Second Edition", CLSI EP5-A3 as guidance.

Day-to-Day Imprecision

To investigate day-to-day precision five (5) levels of Nova Max Creatinine Aqueous Solutions were used. Two (2) Nova Max Creat eGFR Monitors and three (3) Nova Max Creat eGFR Creatinine-Test Strip lots were tested in the study.

Each level of the aqueous solutions was analyzed in duplicates, twice a day over twenty (20) days. The results (presented in **Table 2**) met the acceptance criteria indicating that the day-to-day precision of the Creatinine assay on the Nova Max Creat eGFR Monitoring Systems is clinically acceptable.

Table 2, Day-to-Day Imprecision Summary

Aqueous Solution		Test Strip Lot 1	Test Strip Lot 2	Test Strip Lot 3
Level 1	Mean, mg/dL	0.56	0.57	0.58
	SD	0.06	0.06	0.06
Level 2	Mean, mg/dL	1.33	1.35	1.37
	SD	0.06	0.08	0.08
Level 3	Mean, mg/dL	2.58	2.65	2.66
	CV (%)	5.00	4.64	4.93
Level 4	Mean, mg/dL	4.13	4.14	4.09
	CV (%)	4.89	4.98	4.98
Level 5	Mean, mg/dL	6.03	5.97	6.04
	CV (%)	4.85	4.99	4.87

Within-run Imprecision

To investigate the precision using whole blood, five (5) blood specimens with creatine concentrations spanning the measurement range were tested. Five (5) Nova Max Creat eGFR Monitors and three (3) Nova Max Creat eGFR Creatinine-Test Strip lots were used in the study. The results (presented in **Table 3**) met the acceptance criteria, indicating that the Nova Max Creat eGFR System report clinically acceptable precision.

Table 3, Within-run Imprecision Summary

Whole Blood Specimens		Test Strip Lot 1	Test Strip Lot 2	Test Strip Lot 3
Level 1	Mean, mg/dL	0.47	0.47	0.49
	SD	0.05	0.06	0.06
Level 2	Mean, mg/dL	0.82	0.83	0.83
	SD	0.06	0.06	0.06
Level 3	Mean, mg/dL	1.68	1.68	1.66
	SD	0.09	0.10	0.10
Level 4	Mean, mg/dL	2.81	2.88	2.83
	CV (%)	4.6%	4.4%	4.8%

Level 5	Mean, mg/dL	5.83	5.88	5.97
	CV (%)	4.7%	5.0%	4.9%

Flex Studies

Nova Biomedical conducted the following flex studies to validate the robustness of the Nova Max Creat eGFR Monitoring System:

1. Short sample
2. Used Nova Max Creat eGFR Creatinine-Test Strips
3. Incorrect test strips
4. Moving during analysis
5. Atypical positions
6. Removing Nova Max Creat eGFR Creatinine-Test Strips during the analysis
7. Double dosing
8. Delayed analysis
9. Flicking
10. Damaged Strip
11. Incorrect Nova Max Creat eGFR Creatinine Control Solutions storage
12. Uncapped Nova Max Creat eGFR Creatinine Control Solutions
13. Extreme Environmental Conditions
14. Improper sampling

The results of the Flex Studies were determined to meet the Acceptance Criteria and error codes were correctly generated (where applicable) as specified in the Instructions for Use Manual.

Clinical Performance

Nova Biomedical conducted a clinical study in the hands of lay users. The clinical study was conducted across two (2) sites with a total of 532 subjects. Measurements on fingerstick samples taken by lay users using the Nova Max Creat eGFR Monitoring System were compared to venous plasma creatinine results measured by laboratory operators using an IDMS traceable comparative method.

The Pearson correlation coefficient (r) between the fingerstick blood readings obtained by lay users and the corresponding comparative method readings obtained by laboratory operators was calculated using least squares linear regression and is displayed in **Table 4**.

Table 4, Creatinine Linear Regression Analysis Summary

Slope:	0.9832
Y-Intercept:	0.0073
Correlation Coefficient (r):	0.9951

The bias between the capillary whole blood creatinine readings from the Nova Max Creat eGFR Monitoring System and the venous plasma creatinine readings measured by the comparative method was evaluated and shown in **Table 5**.

Table 5, Within Clinical Study Accuracy (Bias/Bias%)

Less than 2 mg/dL SD ≤ 0.2 mg/dL	Greater than 2 mg/dL CV ≤ 10%
97.87%	95.36%

The results showed that the Nova Max system's measurements were in strong agreement with the comparative method, meeting the clinical accuracy acceptance criteria in the hands of lay users.

Table 6: Comparison of Predicate and Proposed Devices

	Predicate Device: Nova StatSensor Creatinine Hospital Meter System	**Subject Device: Nova Max Creat GFR Monitoring System**
Intended Use and Indications for Use	The StatSensor Creatinine Meter is intended for in vitro diagnostic use by health care 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.	The Nova Max Creat eGFR Monitoring System is comprised of the Nova Max Creat eGFR Monitor and the Nova Max Creat eGFR Test Strips. The Nova Max Creat eGFR Monitoring System is intended for in vitro diagnostic use for the quantitative measurement of creatinine and estimation of glomerular filtration rate (eGFR) in fresh capillary whole blood obtained from the fingertip of adult patients aged 18 and above. The system is intended for single patient home use by prescription only and should not be shared. It is intended for use by patients as an aid to monitor kidney function on the order of a treating healthcare professional.
Intended Use Environment	Prescription use, point-of-care settings	Home use by prescription
Hand-held meter	Yes	Same
Test Measured/Reported Parameters	Creatinine and eGFR	Creatinine and eGFR
Operating Principle	Enzyme, Amperometry	Same
eGFR equations	CKD-EPI (2009), MDRD and Cockcroft-Gault equation	CKD-EPI 2021 equation
Sample Type	Capillary, Venous and Arterial whole blood specimen	Fingertip capillary whole blood specimen
Sample Volume	1.2 µL	Same
Sample Application	Test strip capillary draw	Same
Measurement Range for Creatinine	0.3 - 12.0 mg/dL (1 significant digit)	0.30 - 7.00 mg/dL (2 significant digits)
Test Range for eGFR calculated using the CKD-EPI equation	15 - 90 mL/min/1.73 m^2	Same
Analysis Time	30 seconds	Same
Hematocrit Range	30% to 60%	20% to 70%
Quality Control	Three Levels	Two Levels
Linearity	Five Levels	None
Calibration	Automatic, No Calibration Code	Same

Location of the test strip port	Bottom of the meter	Same
Physical dimensions of the meter	153 mm (6.0 in) x 82.5 mm (3.25 in) x 46 mm (1.8 in)	95.25 mm (3.75 in) x 61.98 mm (2.44 in) x 18.80 mm (0.74 in)
Weight	360 grams	90 grams
Menu navigation	Color touch screen display	Same
Power/Energy Source	3.7 V Li-Polymer battery (Rechargeable/Replaceable)	3.7 V Li-Polymer battery (Rechargeable/Non-Replaceable)
Battery Charging	Charged via a Desk-mount Docking/ Charging Station	Charged like a cell phone, using an external power supply connected to an electric outlet, and a charging cable connecting the power supply to the monitor.
Meter Memory	1000 patient results 200 QC results 4000 Operators	400 Patient and/or QC Results
Data Transfer	Via Docking Station Ethernet Connectivity	No data transfer is available
Operating Temperature Range	59°F to 104°F (15°C to 40°C)	Same
Operating Humidity Range	10% to 90% relative humidity	Same
Operating Altitude Range	Up to 15,000 feet (4572 meters)	Up to 12,000 feet (3658 meters)
Test Strip Storage Temperature (Closed Vial)	35.6°F to 46.4°F (2°C to 8°C)	Same
Test Strip Shelf Life	24 months	Same
Control Solutions Storage Temperature (Closed Vial)	35.6°F to 46.4°F (2°C to 8°C)	Same
Control Solutions Shelf Life	24 months	Same

Conclusion

Based on the performance data provided with this submission, it can be concluded that the Nova Max Creat eGFR Monitoring System has been demonstrated to be safe, and effective for its intended use for monitoring of kidney health in the intended use setting. The similarities in the intended use and technological characteristics between the proposed Nova Max Creat eGFR Monitoring System and the FDA cleared predicate device, StatSensor Creatinine Hospital Meter System, support that the two devices are substantially equivalent.