



January 9, 2026

Nova Biomedical Corporation
Glen D'Souza
Regulatory Affairs Specialist - II
200 Prospect Street
Waltham, Massachusetts 02454

Re: K252206

Trade/Device Name: Nova Allegro UACR Assay, Nova Allegro Analyzer
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Code: CGX, JIQ, JQT
Dated: July 10, 2025
Received: July 14, 2025

Dear Glen D'Souza:

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

Indications for Use

510(k) Number (if known)
K252206

Device Name
Nova Allegro UACR Assay
Nova Allegro Analyzer

Indications for Use (Describe)

The Nova Allegro urine albumin creatinine ratio (UACR) assay is intended for the quantitative determination of albumin, creatinine, and the albumin/creatinine ratio (UACR) in human urine. The measurement of urine albumin, creatinine, and albumin/creatinine ratio aids in the early diagnosis of nephropathy.

The Nova Allegro Analyzer is intended for in vitro diagnostic use in clinical laboratory and near-patient testing (point-of-care) settings for the quantitative determination of Nova Allegro Assays using Nova Allegro Test Cartridges.

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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510k Summary

510(k) Owner: Nova Biomedical Corporation

Registration Number: 1219029

510k Number: K252206

Address: 200 Prospect Street
Waltham, MA, 02454 USA
Phone: 781-894-0800

Contact Person: Glen D'Souza
Regulatory Affairs Specialist - II
Nova Biomedical Corporation

Proprietary Name: Nova Allegro UACR Assay
Nova Allegro Analyzer

Predicate Device: Nova Allegro Analyzer (K221813)
Nova Allegro UACR Assay (K221813)

Classification and Product Code(s):

Classification Name	Regulation #	Class	Product Code
Creatinine Test system	862.1225	II	CGX
Urinary protein or albumin (nonquantitative) test system	862.1645	I	JIQ
Analyzer	862.2400	I	JQT

Device Description:

Nova Allegro UACR Assay

The Nova Allegro UACR Assay is a completely automated assay that functions with the Nova Allegro Analyzer for the determination of albumin and creatinine and the calculation of UACR in human urine. The Nova Allegro UACR Assays are performed sequentially using a single Allegro UACR test cartridge. The Allegro UACR Test Cartridge contains all of the reagents for measuring albumin and creatinine. Allegro UACR Controls are used to monitor the performance of the Nova Allegro UACR Test Cartridge and Allegro analyzer.

Nova Allegro Analyzer

The Nova Allegro Analyzer is a compact, point-of-care analyzer that features a clinically important menu of measured and calculated tests. All tests are measured with disposable, ready-to-use cartridges. The analyzer supports multiple wavelengths that are used to measure the assay of interest. The analyzer consists of the following key systems/components that the user interacts with:

- Two analytical bays where the single use test cartridges are analyzed
- Color Touchscreen Display
- Barcode Scanner
- Printer
- Data Export Options

- Ethernet Connection
- USB Port

Indications for Use:

The Nova Allegro urine albumin creatinine ratio (UACR) assay is intended for the quantitative determination of albumin, creatinine, and the albumin/creatinine ratio (UACR) in human urine. The measurement of urine albumin, creatinine, and albumin/creatinine ratio aids in the early diagnosis of nephropathy.

The Nova Allegro Analyzer is intended for in vitro diagnostic use in clinical laboratory and near-patient testing (point-of-care) settings for the quantitative determination of Nova Allegro Assays using Nova Allegro Test Cartridges.

Principle of Measurement:

When a urine sample containing albumin is reacted with antibody specific for albumin, an antibody albumin complex is formed. The amount of complex is in direct proportion to the amount of albumin in the sample. The albumin is then quantified using a stored calibration curve.

The Benedict/Behre chemistry is the basis for the creatinine assay. 3,5-dinitrobenzoic acid at high pH reacts with creatinine to form a colored complex. The colored complex is in direct proportion to the amount of creatinine in the sample which is determined from a stored calibration curve. The albumin to creatinine ratio, UACR, is then calculated and displayed on the Nova Allegro Analyzer.

Summary of Performance Testing:

The modification introduced to the device did not impact precision, linearity, analytical specificity, analytical sensitivity, or accuracy. Those characteristics are the same as described in K221813.

The following studies were conducted to demonstrate the UACR Sample Volume Verification System and the Allegro UACR Assay Analyzer System work as intended.

Flex studies

- Bubbles In Specimen
- Capillary Sampling
- Dropped or Damaged Cartridge
- Empty Capillaries
- Incorrect Capillary

Sample Volume Verification System Validation

Predicate Device Comparison:

The substantial equivalence comparison information is tabulated below:

Characteristic	Predicate:	Proposed:
UACR Assay	K221813- Nova Allegro Analyzer Nova Allegro UACR Assay	Nova Allegro Analyzer Nova Allegro UACR Assay

Intended Use	The Nova Allegro urine albumin creatinine ratio (UACR) assay is intended for the quantitative determination of albumin, creatinine, and the albumin/creatinine ratio (UACR) in human urine. The measurement of urine albumin, creatinine, and albumin/creatinine ratio aids in the early diagnosis of nephropathy.	Same
Intended Users	Professional	Same
Sample type	Human Urine – fresh and refrigerated	Same
Sample Volume	25 µL	Same
Measurement Range - Albumin	5.0 - 300 mg/L	Same
Measurement Range - Creatinine	15.0 - 500 mg/dL	Same
Measurement Range - ACR	1.0 - 2,000 mg/g	Same
Test Principle – Albumin	Immunoturbidimetric measurement	Same
Test Principle – Creatinine	alkaline colorimetric	Same
Analysis Time	≤7 Minutes	Same

Substantial Equivalence

The Nova Allegro UACR Assay and Nova Allegro Analyzer performed as intended. The Nova Allegro UACR Assay and Nova Allegro Analyzer displayed substantial equivalence to the legally marketed predicate device, Nova Allegro UACR Assay and Nova Allegro Analyzer (K221813).

The submitted information in this 510(k)-submission application is complete.

The data supports the 510(k) substantial equivalence approval decisions.