November 19, 2024

Nova Biomedical Corporation
Cesidio Tempesta
Regulatory Affairs Manager
200 Prospect St.
Waltham, Massachusetts 02454

Re: K221813
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: April 5, 2024
Received: April 8, 2024

Dear Cesidio Tempesta:

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 Division 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)*
K221813

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.

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510(k) Summary

510(K) K221813

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: Cesidio Tempesta
Date Prepared: November 18, 2024

Proprietary Name:

Nova Allegro Analyzer

Nova Allegro UACR Assay

Common or Usual Name:

Analyzer
UACR Test

Classification Name

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

Predicate Device:

K072409 – Afinion ACR and ACR Control

Device Description:

Nova Allegro UACR Assay

The Nova Allegro UACR Assay is a completely automated assay for the determination of albumin and creatinine in human urine. The results are used to calculate the UACR (Urine Albumin to Creatinine Ratio). Nova Allegro UACR Test Cartridges are the key element a user interacts with to determine the albumin and creatinine levels in a human urine sample. The main components of the Test Cartridge are the Capillary, the reaction chamber, and the barcode label.

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

Sample Types:

Urine with no preservative

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.

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:

Bench testing and point-of-care clinical performance studies were completed to demonstrate that the Nova Allegro UACR Assay achieves its intended performance during normal conditions of use in its intended environment and in its intended use population. Testing is summarized as follows:

Linearity Testing

A study was performed to validate the Nova Allegro UACR Assay linearity for albumin and creatinine.

One (1) Nova Allegro Analyzer, one (1) lot of Nova Allegro UACR Test Cartridges, and UACR control solutions (Level 1 & Level 2) were used in this study. UACR control solutions and two (2) urine pools containing low and very high albumin and creatinine concentrations were analyzed on the Nova Allegro Analyzer and in duplicate on the Comparative Method (CM) to assess linearity.

The linearity data meets the acceptance criteria when compared to the CM. The data indicates that the Nova Allegro System reports linear albumin and creatinine test results using urine specimens across the reportable range.

Hook Effect

A study was performed to validate and determine at what concentration level the Nova Allegro UACR assay exhibits a characteristic “Hook Effect” when measuring albumin. A Hook Effect is a phenomenon that gives falsely low results in the presence of excess amount of analyte. This type of interference is common with homogenous immunoassays. The result reported here is specific to the antibody used in the Nova Allegro UACR assay.

Based upon the testing using both pooled urine specimens and calibrator matrix, the “Hook Effect” was determined to occur above 50,000 mg/L, meeting the acceptance criteria. This is 10 times higher than the acceptance criteria of 5,000 mg/L and approximately 167 times greater than the upper reportable measurement range for the assay. Samples between 301 and 50,000 mg/L of albumin will report “UAlb >300 mg/L” on the Allegro analyzer.

Detection Limit

A study was performed to assess the low-level test performance with the Nova Allegro UACR Assay. Limit of Blank (LOB), Limit of Detection (LOD), and Limit of Quantification (LOQ) are terms to describe the smallest concentration of an analyte that can be reliably measured by an analytical procedure.

Three (3) Nova Allegro Analyzers and three (3) lots of Nova Allegro UACR Test Cartridges were used in the study. Sixty (60) replicate measurements were tested to determine LOB and LOD and thirty six (36) replicate measurements were tested to determine LOQ.

Limit of Blank (LOB), Limit of Detection (LOD), and Limit of Quantification (LOQ) were calculated from the results. The study demonstrates that the LOB, LOD and LOQ results for Albumin and Creatinine measurements by the Nova Allegro UACR Assay are all below the lower limit of the claimed measurement range.

Interference Testing

Testing was performed for specific interfering substances with the Allegro UACR Assay, and to assess the impact of urine pH. Six (6) Nova Allegro Analyzers and four (4) lots of Nova Allegro UACR Test Cartridges were used in the study.

Ten (10) replicate UACR tests were performed on prepared urine specimens containing potential interfering substances as well as control specimens without the interfering substance.

A test substance was considered to interfere with the assay if the absolute difference between the mean test value and the mean control value was greater than 10%.

For any substance found to interfere with the assay results, serial dilutions were performed on test specimens to determine the highest concentration of interfering compound that does not interfere with the measurement.

Table 1 contains the list of substances that were demonstrated to have no significant interference (greater than 10% effect) on the Albumin or Creatinine test results.

Table 1: Tested Substances That Demonstrated No Significant Interference

Test Substance	Concentration	Test Substance	Concentration
Acetaminophen-glucuronide	1050 mg/dL	Citric Acid	75 mg/dL
Acetaminophen	20 mg/dL	Fructose	100 mg/dL
Ethyl Acetoacetate	84 mg/dL	Lactose	10 mg/dL
Metformin	400 mg/dL	Sodium Bicarbonate	1500 mg/dL
Glyburide	1.48 mg/dL	Digoxin	0.03 mg/dL
IgG	2000 mg/dL	Sodium Phosphate	500 mg/dL
Acetone	80 mg/dL	Ammonium Chloride	100 mg/dL
Myoglobin	2 mg/dL	Sodium Nitrite	10 mg/dL
Beta-2-Microglobulin	2 mg/dL	Calcium Chloride	180 mg/dL
Red Blood Cells	50 cells/µL	Creatine	1000 mg/dL
IgA	25 mg/dL	Galactose	80 mg/dL
Transferin	200 mg/dL	Glycine	450 mg/dL
Insulin	500 uU/mL	Lithium Acetoacetate	250 mg/dL
ß-Hydroxbutyric Acid	590 mg/dL	Sodium Acetate	2.25 mg/dL
Ibuprofen	200 mg/dL	Sodium Nitrate	10 mg/dL
Glucose	4500 mg/dL	Theophylline	100 mg/dL
Hemoglobin	10 mg/dL	Uric acid	150 mg/dL
Urea	3000 mg/dL	Trichlormethiazide	2 mg/dL
Albumin	1000 mg/dL	Glybenclamide	1.5 mg/dL
Creatinine	620 mg/dL	Urobilinogen	20 mg/dL

Table 2 contains the list of substances that were demonstrated to have a clinical interference (greater than 10% effect) on the Albumin or Creatinine test results.

Table 2: Interfering Substances

Interfering Substance	Highest tested concentration that does not cause interference	
	ALB	CREAT
Oxalic Acid	40 mg/dL	70 mg/dL
Conjugated Bilirubin	4.2 mg/dL	20 mg/dL
Riboflavin -Vitamin B2	2.5 mg/dL	10 mg/dL
Sodium Chloride	2000 mg/dL	5500 mg/dL
Potassium Chloride	1200 mg/dL	1500 mg/dL
Leukocytes	2500/ul	1250/ul
Ascorbic Acid	300 mg/dL	100 mg/dL

Note: Urines with pH between 4.3 – 10.0 exhibited no interference. Urines with a pH of 4.0 exhibited a clinical interference for samples with low levels of Albumin.

Note: Urine with specific gravity between 1.003 and 1.048 exhibited no clinical interference.

Note: Albumin, Creatinine and UACR results may be affected in samples with high concentrations of bilirubin and/or Vitamin B2 where the samples may appear discolored. Do not use the Allegro UACR Assay if the urine sample is discolored and not yellow or clear.

Method Comparison

Point-of-Care (POC) Method Comparison studies on fresh urine specimens were conducted within four (4) different POC sites using methods described in CLSI “Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition”, CLSI EP9-A3.

A total of eight (8) Nova Allegro Analyzers (2 per site) and three (3) lots of Allegro UACR Test Cartridges were used in the study.

At each site, a minimum of 3 operators conducted the testing (minimum 120 comparative specimens on two (2) Allegro Analyzers at each site).

A small percentage of test specimens were altered to cover the analytical measurement range of the Nova Allegro UACR Assay for albumin and creatinine.

Specimens were tested over at least a 20-day period to ensure system day-to-day variability was considered. Specimens run on the Nova Allegro Analyzers using the Nova Allegro UACR Assay were compared to the Siemens Dimension EXL 200 Integrated Chemistry System utilizing Dimension® Flex® reagent cartridge MALB, Dimension calibrator cartridge MALB CAL (Traceable to IFCC International Reference Preparation for Plasma Proteins), Dimension Flex Reagent Cartridge CRE2, and Dimension CHEM 1 CAL (Traceable to NIST SRM 914 and verified with NIST SRM 967) as the CM method. The combined test results for the four (4) POC sites participating in the Method Comparison study are in the following tables:

Table 3: Results Summary, Urine Albumin, Nova Allegro vs. CM - Combined

	Albumin		Regression Analysis				
Site	Number of samples within measurement range	Altered samples	Sample range Allegro (min-max)		Slope	Intercept	r
1	149	10	5	292	1.000	0.257	0.998
2	164	11	5	295	0.988	0.762	0.998
3	113	10	5	300	0.967	0.692	0.998
4	109	10	5	295	0.984	1.179	0.998
ALL	535	41	5	300	0.983	0.858	0.998

Table 4: Results Summary, Urine Creatinine, Nova Allegro vs. CM - Combined

	Creatinine		Regression Analysis				
Site	Number of samples within measurement range	Altered samples	Sample range Allegro (min-max) mg/dL		Slope	Intercept	r
1	188	0	18	498	0.937	5.322	0.998
2	201	0	16	451	0.939	4.112	0.996
3	136	0	16	426	0.995	-0.569	0.997
4	128	0	24	397	1.010	-0.600	0.996
ALL	653	0	16	498	0.949	3.775	0.997

Table 5: Results Summary, UACR, Nova Allegro vs. CM – Combined

	UACR ratio		Regression Analysis				
Site	Number of samples that returned exact result[#]	Altered samples	Sample range Allegro (min-max)		Slope	Intercept	r
1	148*	10	3	544	1.011	0.699	0.997
2	161	11	2	1161	1.017	0.454	0.998
3	113	10	1	1592	0.9762	1.724	0.997
4	109	10	3	776	1.009	1.651	0.998
ALL	531*	41	1	1592	0.995	1.101	0.997

Precision

Total Imprecision of the Nova Allegro UACR Assay in the hands of operators was assessed using methods described in CLSI "Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guidelines – Second Edition," CLSI EP5-A3 as guidance.

A total of eight (8) Nova Allegro Analyzers (2 per site) and three (3) lots of Allegro UACR Test Cartridges were used in the study.

Table 6: Repeatability

Microalbumin

Urine Samples	Repeatability										
	Site 1		Site 2		Site 3		Site 4		Overall		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	% CV
Urine 1	125	4.4	125	4.5	124	5.0	120	4.0	123	4.5	3.6%
Urine 2	134	5.1	131	5.9	131	4.8	130	5.1	131	5.3	4.0%
Urine 3	251	8.4	248	8.6	251	8.0	237	10.5	247	8.9	3.6%

Creatinine

Urine Samples	Repeatability										
	Site 1		Site 2		Site 3		Site 4		Overall		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	% CV
Urine 1	62	2.2	61	2.4	59	2.9	59	2.2	60	2.4	4.0%
Urine 2	460	13.2	453	15.6	440	12.3	454	14.0	452	13.8	3.1%
Urine 3	82	2.3	81	2.2	79	3.0	79	3.2	80	2.7	3.4%

UACR

Urine Samples	Repeatability										
	Site 1		Site 2		Site 3		Site 4		Overall		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	% CV
Urine 1	202	4.2	203	5.5	210	5.0	202	5.5	204	5.1	2.5%
Urine 2	29	0.6	29	0.8	30	0.8	29	0.7	29	0.7	2.5%
Urine 3	308	6.1	308	6.6	316	7.9	302	9.1	308	7.5	2.4%

Table 7: Between Run/Operator

Microalbumin

Urine Samples	Between Run/Operator										
	Site 1		Site 2		Site 3		Site 4		Overall		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	% CV
Urine 1	125	2.8	125	3.9	124	2.1	120	3.7	123	3.2	2.6%
Urine 2	134	0.9	131	0.0	131	0.0	130	0.0	131	0.5	0.3%
Urine 3	251	6.0	248	3.0	251	3.2	237	0.0	247	3.7	1.5%

Creatinine

Urine Samples	Between Run/Operator										
	Site 1		Site 2		Site 3		Site 4		Overall		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	% CV
Urine 1	62	1.3	61	1.8	59	0.8	59	1.4	60	1.4	2.3%
Urine 2	460	0.0	453	2.8	440	3.9	454	0.0	452	2.4	0.5%
Urine 3	82	1.5	81	2.2	79	2.9	79	1.8	80	2.2	2.7%

UACR

Urine Samples	Between Run/Operator										
	Site 1		Site 2		Site 3		Site 4		Overall		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	% CV
Urine 1	202	1.4	203	0.0	210	2.6	202	3.8	204	2.4	1.2%
Urine 2	29	0.2	29	0.0	30	0.0	29	0.3	29	0.2	0.6%
Urine 3	308	0.0	308	5.9	316	9.7	302	0.0	308	5.7	1.8%

Table 8: Between Lot/Day

Microalbumin

Urine Samples	Between Lot/Day										
	Site 1		Site 2		Site 3		Site 4		Overall		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	% CV
Urine 1	125	1.4	125	1.7	124	1.4	120	1.8	123	1.6	1.3%
Urine 2	134	0.0	131	2.1	131	2.7	130	0.0	131	1.7	1.3%
Urine 3	251	0.0	248	1.5	251	0.0	237	1.9	247	1.2	0.5%

Creatinine

Urine Samples	Between Lot/Day										
	Site 1		Site 2		Site 3		Site 4		Overall		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	% CV
Urine 1	62	0.7	61	1.0	59	0.0	59	0.0	60	0.6	1.0%
Urine 2	460	1.8	454	3.9	440	0.9	454	0.0	452	2.2	0.5%
Urine 3	82	0.0	81	0.0	79	0.0	79	0.7	80	0.4	0.5%

UACR

Urine Samples	Between Lot/Day										
	Site 1		Site 2		Site 3		Site 4		Overall		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	% CV
Urine 1	202	0.0	203	0.0	210	1.9	202	1.0	204	1.1	0.5%
Urine 2	29	0.0	29	0.2	30	0.5	29	0.2	29	0.3	1.1%
Urine 3	308	0.0	308	1.0	316	1.0	302	0.0	308	0.7	0.2%

Table 9: Within Lab

Microalbumin

Urine Samples	Within Laboratory										
	Site 1		Site 2		Site 3		Site 4		Overall		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	% CV
Urine 1	125	5.6	125	5.7	124	5.5	120	5.8	123	5.6	4.6%
Urine 2	134	5.0	131	6.3	131	5.4	130	5.0	131	5.4	4.1%
Urine 3	251	11.2	248	9.2	251	9.9	237	11.2	247	10.4	4.2%

Creatinine

Urine Samples	Within Laboratory										
	Site 1		Site 2		Site 3		Site 4		Overall		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	% CV
Urine 1	62	2.9	61	2.8	59	2.9	59	2.9	60	2.9	4.8%
Urine 2	460	13.6	453	18.3	440	13.6	454	14.7	452	15.2	3.4%
Urine 3	82	3.1	81	3.0	79	3.9	79	4.1	80	3.6	4.5%

UACR

Urine Samples	Within Laboratory										
	Site 1		Site 2		Site 3		Site 4		Overall		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	% CV
Urine 1	202	4.5	203	5.5	210	7.0	202	6.7	204	6.0	2.9%
Urine 2	29	0.7	29	0.9	30	1.1	29	0.7	29	0.9	3.0%
Urine 3	308	7.0	308	8.4	316	14.1	302	8.7	308	9.9	3.2%

Table 10: Between Site

Microalbumin

Control Levels	Between Site								
	Lot 1		Lot 2		Lot 3		Overall		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	% CV
Control 1	47	0.4	47	0.5	46	0.4	47	0.5	1.0%
Control 2	153	0.0	153	3.7	151	1.9	152	2.4	1.6%

Creatinine

Control Levels	Between Site								
	Lot 1		Lot 2		Lot 3		Overall		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	% CV
Control 1	85	0.0	85	1.4	85	0.4	85	0.8	1.0%
Control 2	216	1.9	216	2.40	215	1.6	216	2.0	0.9%

UACR

Control Levels	Between Site								
	Lot 1		Lot 2		Lot 3		Overall		
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	% CV
Control 1	55	0.7	55	0.5	55	0.7	55	0.6	1.2%
Control 2	71	0.5	71	0.9	70	1.0	71	0.8	1.2%

Table 11: Comparison of Predicate and Proposed Devices

Characteristic	Predicate:	Proposed:
UACR Assay	**K072409 – Afinion ACR and ACR Control**	**K221813 Nova Allegro UACR Assay**
Intended Use	Afinion™ ACR is an in vitro diagnostic test for quantitative determination of albumin, creatinine and albumin/creatinine ratio (ACR) in human urine. The measurement of urine albumin, creatinine and albumin/creatinine ratio aids in the early diagnosis of nephropathy. Afinion™ ACR Control is a assayed in vitro diagnostic quality control material used to confirm that the Afinion™ ACR and the Afinion™ AS100 Analyzer System is working properly and provides reliable results.	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.
Measurement Range - Albumin	5.0- 200.0 mg/L	5.0 - 300 mg/L
Measurement Range - Creatinine	16.4-339.9 mg/dL	15.0 - 500 mg/dL
Measurement Range - ACR	1.0-1250.0 mg/g	1.0 - 2,000 mg/g
Test Principle – Albumin	Immunometric membrane flow-through principle	Immunoturbidimetric measurement
Test Principle – Creatinine	enzymatic colorimetric	alkaline colorimetric
Type of Test	Point-of-Care quantitative in-vitro diagnostic test	Same
Intended Users	Prescription Use.	Prescription Use
Sample Volume	3.5 µL	25 µL
Assay Time	5 min 35 seconds	≤7 Minutes
Calibration	Built In	Same

Substantial Equivalence

The results obtained from the nonclinical and clinical evaluations confirmed the accuracy of the Nova Allegro UACR Assay when used in the health care settings outlined in its intended use.

The Nova Allegro UACR Assay displayed substantial equivalence to the legally marketed predicate device, Afinion ACR and Afinion ACR Control (K072409).

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

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