510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K252206

B Applicant

Nova Biomedical Corporation

C Proprietary and Established Names

Nova Allegro UACR Assay, Nova Allegro Analyzer

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
CGX	Class II	21 CFR 862.1225 - Creatinine Test System	CH - Clinical Chemistry
JIQ	Class I, meets the limitations of exemptions in 862.9(c)(9)	21 CFR 862.1645 - Urinary protein or albumin (nonquantitative) test system	CH - Clinical Chemistry
JQT	Class I	21 CFR 862.2400 – Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use	CH- Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Modification to a cleared device

B Measurand:

Urine Albumin and Creatinine

C Type of Test:

Immunoturbidimetric (Albumin)
Colorimetric (Creatinine)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Nova Allegro Analyzer

IV Device/System Characteristics:

A Device Description:

The assay is unchanged since it was cleared in K221813.

The instrument cleared in K221813 was modified to include a control feature to ensure the correct sample volume.

B Principle of Operation:

Same as described in K221813.

C Instrument Description Information:

1. Instrument Name:

   Same as K221813.

2. Specimen Identification:

   Same as described in K221813.

3. Specimen Sampling and Handling:

   A single-use, disposable capillary sample collection device is used to obtain and load the sample. The capillary sample collection device containing the sample is loaded onto the test cartridge, then the test cartridge is placed into the sample bay within 1 minute of sample collection and the start icon is pressed to start analysis. For the UACR assay, the instrument has a control feature, an integrated Allegro Sample Volume Verification System to ensure the correct sample volume.

4. Calibration:

   Same as described in K221813.

5. Quality Control:

   Same as described in K221813.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Nova Allegro UACR Assay, Nova Allegro Analyzer

B Predicate 510(k) Number(s):
K221813

C Comparison with Predicate(s):

Device & Predicate Device(s):	K252206	K221813
Device Trade Name	Nova Allegro UACR Assay, Nova Allegro Analyzer	Same
General Device Characteristic Similarities		
Intended Use/Indications For Use	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
Matrix	Urine	Same
Intended Users	Professional	Same
General Device Characteristic Differences		
Sample Volume Verification System	Yes	No

VI Standards/Guidance Documents Referenced:

- ISO 14971 Third Edition 2019-12. Medical Devices; Application of risk management to medical devices.
- IEC 62304 Edition 1.1 2015-06 Consolidated Version; Medical device software-Software life cycle processes.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   This was previously established in K221813.

2. Linearity:

   This was previously established in K221813.

3. Analytical Specificity/Interference:

   This was previously established in K221813.

4. Assay Reportable Range:

   This was previously established in K221813.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   This was previously established in K221813.

6. Detection Limit:

   This was previously established in K221813.

7. Assay Cut-Off:

   Not applicable

8. Accuracy (Instrument):

   See K221326 Section VII.C.3 Other Clinical Supportive Data.

9. Carry-Over:

   This was previously established in K221813.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   This was previously established in K221813.

2. Matrix Comparison:

   Not Applicable

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable

2. Clinical Specificity:

   Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

Same as described in K221813

F Other Supportive Instrument Performance Characteristics Data:

Sample Volume Verification System
The sample volume verification system was tested and shown to be effective.

Information to support electrical safety and electromagnetic compatibility (EMC) software and cybersecurity was reviewed and found to be acceptable.

The Nova Allegro UACR Assay on the Nova Allegro Analyzer is not impacted by altitude up to 12,000 feet/3650 meters.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.