November 22, 2024

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

Re: K221326
Trade/Device Name: Nova Allegro HbA1c Assay, Nova Allegro Analyzer
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated Hemoglobin Assay
Regulatory Class: Class II
Product Code: LCP, JQT
Dated: April 25, 2024
Received: April 26, 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)*
K221326

Device Name
Nova Allegro HbA1c Assay, Nova Allegro Analyzer

Indications for Use *(Describe)*
The Nova Allegro HbA1c Assay is intended for in vitro diagnostic use on the Nova Allegro Analyzer for the quantitative determination of the glycated Hemoglobin (% hemoglobin A1c) in capillary whole blood obtained from the fingertip. The results from this assay are intended to be used for the monitoring of long-term blood glucose/metabolic control in individuals with diabetes mellitus.

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): K221326/CW220003

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 22, 2024**

Proprietary Name:
Nova Allegro Analyzer
Nova Allegro HbA1c Assay

Common or Usual Name:
Analyzer
HbA1c Test

Classification Name

Classification Name	Regulation #	Class	Product Code
Glycosylated Hemoglobin Assay	864.7470	II	LCP
Analyzer	862.2400	I	JQT

Predicate Device:
K171650 – Alere Afinion HbA1c Assay on the Afinion 2 Analyzer

Device Description:

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, and are easily performed by non-technical personnel. 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

Nova Allegro HbA1c Assay

The Allegro HbA1c Assay is a completely automated assay for the determination of the HbA1c in human whole blood and the calculation of estimated average glucose (eAG). Nova Allegro HbA1c Test Cartridges are the key element a user interacts with to obtain the HbA1c concentration in a Capillary finger-stick whole blood sample. The main components of the Test Cartridge are the Capillary that is used to obtain the Capillary finger-stick whole blood specimen and present it to the Test Cartridge and the reaction chamber. The Test Cartridge has a barcode label with lot specific information.

Sample Types:

Capillary whole blood (from finger stick)

Intended Use:

The Nova Allegro HbA1c Assay is intended for in vitro diagnostic use on the Nova Allegro Analyzer for the quantitative determination of the glycated Hemoglobin (% hemoglobin A1c) in capillary whole blood obtained from the fingertip. The results from this assay are intended to be used for the monitoring of long-term blood glucose/metabolic control in individuals with diabetes mellitus.

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:

A whole blood sample containing Hemoglobin A1c and Total Hemoglobin are nonspecifically absorbed to latex particles. The anti-human mouse HbA1c antibody reacts with this forming a complex. Agglutination occurs when polyclonal antibody specifically reacts with the mouse antibody bound to the Hemoglobin A1c on the surface of the latex particles. The amount of agglutination is measured as absorbance. The HbA1c value is obtained from a stored calibration curve and displayed on the Nova Allegro Analyzer.

Summary of Performance Testing:

Bench testing and point-of-care clinical performance studies were completed in physician's offices to demonstrate that the Nova Allegro HbA1c 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

Testing was performed to validate the Nova Allegro HbA1c Assay (Test Method) linearity when compared to a reference method. Eleven (11) linearity specimens were tested randomly on the Nova Allegro Analyzer. The same eleven linearity specimens were then analyzed on the reference method.

The resulting linearity data met the acceptance criteria when compared to the reference method across the reportable range of 4.0-14.0 % HbA1c.

Interference Testing

Testing was performed to test for specific interfering substances with the Allegro HbA1c Assay.

Ten (10) replicate HbA1c tests were performed on prepared hemolysate specimens containing potential interfering substances as well as control specimens without the interfering substance.

The test substance was considered to exhibit interference if the absolute difference between the mean test value and the mean control value was greater than 10%.

Based upon the results, all potential interfering substances tested met the acceptance criteria and were demonstrated not to have a clinical interference on HbA1c test results. No significant interference (<10%) was observed up to the following concentration levels:

Table 1: Tested Concentration Levels

Test Substance	Concentration	Test Substance	Concentration
Acetylsalicyclic Acid	65.2 mg/dL	Rifampicin	6.4 mg/dL
Ibuprofen	50.0 mg/dL	Theophylline	10.0 mg/dL
Glyburide	200 mg/dL	vitamin B12	1.2 mg/dL
Cholesterol	1055 mg/dL	Furosemide	7 mg/dL
Acetaminophen	20.0 mg/dL	Gemfibrozil	8 mg/dL
Non-conjugated Bilirubin	60.0 mg/dL	Losartan	6 mg/dL
Conjugated bilirubin	30.0 mg/dL	Nicotinic Acid	70 mg/dL
Ascorbic Acid	6.0 mg/dL	Urea	700 mg/dL
Metformin	4.0 mg/dL	γ-Tocopherol	10 mg/dL
Glucose	1000 mg/dL	Atorvastatin	5 mg/dL
Glipizide	0.2 mg/dL	Intralipid	1000 mg/dL
Chlorpropamide	74.8 mg/dL	Propanolol	0.3 mg/dL
Tolbutamide	64 mg/dL	Uric Acid	30.0 mg/dL
Acarbose	60 mg/dL	Acetylcysteine	166 mg/dL
Captopril	0.6 mg/dL	Cefoxitin	650 mg/dL
Rheumatoid Factor	572 IU/ml	Doxycyclin	5.0 mg/dL
Ampicillin	100 mg/dL	Immunoglobulin	2.0 g/dL
Cyclosporine	0.5 mg/dL	Methyldopa	2.25 mg/dL
Heparin	5 U/mL	Ozempic (semaglutide)	0.192 mg/dL
Levodopa	2.0 mg/dL	Protein (Total)	21000 mg/dL
Metronidazole	20.0 mg/dL	Salicylic acid	59 mg/dL
Phenylbutazone	40.0 mg/dL	Triglycerides	1520 mg/dL

Total Hemoglobin Interference Testing

Testing was performed to test for Total Hemoglobin (HGB) Interference on the Allegro HbA1c Assay.

The tested Total Hemoglobin (HGB) was considered non-interfering if the difference between the mean of the HbA1c measured at the tested HGB level and that of the neat HbA1c sample is less than 10%. All tested HGB levels met the Acceptance Criteria and were demonstrated to have no significant clinical interference on the measured A1c test results. No clinical interference was identified for total hemoglobin (HGB) levels between 6 and 20 g/dL.

Method Comparison

Method Comparison studies on capillary fingerstick whole blood specimens were conducted. A total of four (4) clinical sites, eight (8) Allegro Analyzers (2 per site) and three (3) lots of Allegro HbA1c Test Cartridges were used in the study. At each site, a minimum of three (3) CLIA-Waived operators conducted the HbA1c capillary testing by running a minimum of 90 specimens.

Samples were tested over a minimum of twenty (20) days to ensure system day-to-day variability was considered. Samples run on the Allegro Analyzers using the Allegro HbA1c assay were compared to a NGSP Certified central laboratory reference method.

The Passing-Bablok regression results are shown in Table 2:

Table 2: Passing-Bablok Regression Results

Site	N	Sample Range Allegro (%)	Slope	Intercept	r
1	156	4.7 - 12.9	0.968	0.261	0.993
2	154	4.6 - 13.2	0.974	0.204	0.993
3	102	5.0 - 13.1	0.983	0.180	0.994
4	114	4.4 - 13.8	0.968	0.203	0.994
Combined	526	4.4 - 13.8	0.972	0.217	0.993

The data indicates that the Nova Allegro System reports substantially equivalent HbA1c test results when using fingerstick whole blood samples when compared to the comparator method.

Precision

Total Imprecision of the Allegro HbA1c Assay in the hands of CLIA Waived professionals was assessed using methods described in CLSI "Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guidelines – Second Edition", CLSI EP5-A3 as guidance.

20-Day Imprecision (Controls)

Two Nova Allegro HbA1c Control Solutions were analyzed for twenty days in duplicate twice a day (total of eighty measurements per sample) at each of the four POC CLIA waived sites, using three HbA1c test cartridge lots and three different untrained operators at each site. Analyses were performed for each individual site and for all sites combined.

		Repeatability		Between-Run/Operator		Between-Day/Lot		Between-Site		Reproducibility	
	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Control 1	5.67	0.091	1.61%	0.037	0.65%	0.034	0.60%	0.045	0.79%	0.113	2.00%
Control 2	9.47	0.175	1.85%	0.035	0.37%	0.118	1.25%	0.112	1.18%	0.242	2.55%

Repeatability (Capillary Fingerstick Blood)

For evaluation of fingerstick precision/repeatability, a second fingerstick specimen was collected and measured for HbA1c on 524 subjects enrolled in the Method Comparison study. Three lots of HbA1c test cartridges, eight analyzers (two at each of four sites) and three different untrained operators were used for the fingerstick precision measurements. Estimates of repeatability are shown below.

			Repeatability	
HbA1C range	N	Mean	SD	%CV
4.0 - 6.0	200	5.50	0.083	1.50%
6.1 – 8.0	169	6.83	0.103	1.51%
8.1 – 10.0	106	8.94	0.171	1.92%
10.1 – 14.0	49	11.32	0.270	2.38%

The data met the acceptance criteria for repeatability and imprecision and indicates that the Allegro Analyzer System reports clinically acceptable HbA1c precision when testing capillary whole blood samples.

Hemoglobin Derivative and Fractions

Testing was performed to test for specific interfering Hemoglobin Derivatives and cross-reactivity of hemoglobin fractions including HbA0, HbA1a, and HbA1b with the Nova Allegro HbA1c.

The test substance will not be considered an interfering substance if the absolute difference between the mean test value and the mean control value is less than 10%. All substances met the Acceptance Criteria and were demonstrated not to have a clinical interference on the measured HbA1c test results. No clinical interference was identified up to the test concentrations reported.

Hemoglobin Derivatives

Testing was performed to assess any possible interference effects of Glycated Albumin, Acetylated Hemoglobin, Labile Hemoglobin, and Carbamylated Hemoglobin on the measured HbA1c test results.

The test substance will not be considered an interfering substance if the absolute difference between the mean test value and the mean control value is less than 10%. All substances met the Acceptance Criteria and were demonstrated not to have a clinical interference on the measured HbA1c test results. No clinical interference was identified with the Allegro HbA1c Assay up to the following test concentrations: 50 mg/mL glycated albumin, 50 mg/mL acetylated hemoglobin, 0.5 mg/mL carbamylated hemoglobin, 20 mg/mL labile hemoglobin

Hemoglobin Fractions

Testing was preformed to assess the cross-reactivity from HbA0, HbA1a, and HbA1b components on the Allegro HbA1c assay.

The test substance was considered an interfering substance if the absolute difference between the mean test value and the mean control value was greater than 10%.

All substances met the Acceptance Criteria and HbA0, HbA1a, and HbA1b were demonstrated not to have a clinical interference on the measured HbA1c test results. No clinical interference was identified up to the test concentrations reported.

Potential interferent	Highest Level Tested with No Significant Interference
HbA0	Up to 93.5%
HbA1a	Up to 1.6%
HbA1b	Up to 1.7%

Hemoglobin Variants

Testing was performed to determine specific Hemoglobin Variant (HbA2, HbC, HbD, HbE, HbS, and HbF) interference on the Allegro HbA1c assay.

The test substance was considered to be an interfering substance if the absolute difference between the mean test value and the mean control value is greater than 10%.

The test results show that there is significant interference due to the presence of fetal hemoglobin at a HbF concentration of > 5.4%. The results from the Nova Allegro HbA1c Assay show that there is no significant interference for samples containing Hemoglobin C (≤ 38.2%), Hemoglobin D (≤41.1%), Hemoglobin E (≤27.9%), Hemoglobin S (≤ 38.6%), and Hemoglobin A2 (≤ 6.5%).

Table 3: Comparison of Predicate and Proposed Devices

Characteristic	Predicate:	Proposed:
Analyzer	**K171650 – Alere Afinion™ 2 Analyzer**	**K221326 - Nova Allegro Nova Allegro Analyzer**
Intended Use	Afinion 2 analyzer is a compact multi-assay analyzer for point-of-care testing, designed to analyze the Alere Afinion™ test cartridges. Afinion 2 system, consisting of Afinion 2 analyzer and Alere Afinion test cartridges is for in vitro diagnostic use only.	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.
Analyzer Function	Assay cartridge processing including pumping, heating, image processing	Same
Cartridge Interface	Physical processing of cartridge (locking, docking, splitting, foil penetration, merging)	Physical processing of cartridge (locking, docking, foil penetration, mixing assay)
User Interface	User display and operating instructions in labeling	Same
Peripheral units	A barcode reader and printer can be connected	Barcode reader and printer integrated into analyzer
Components	Components in metal and injection molded plastics	Same
Dimensions	200 mm W x 186 mm H x 328 mm D 3.4 kg	203 mm W x 356 mm H x 381 mm D 9.1 kg
Connectivity	Ethernet plug incorporated into the analyzer and connectivity software incorporated in the software.	Same
HbA1c Assay	**K171650 – Alere Afinion HbA1c On Afinion 2 Analyzer**	**K221326 - Nova Allegro HbA1c Assay on Nova Allegro Analyzer**
Intended Use	Alere Afinion™ HbA1c is an in-vitro diagnostic test for quantitative determination of glycated hemoglobin (% hemoglobin A1c, % HbA1c) in human whole blood. The measurement of % HbA1c is recommended as a marker of long-term metabolic control in persons with diabetes mellitus	The Nova Allegro HbA1c Assay is intended for in vitro diagnostic use on the Nova Allegro Analyzer for the quantitative determination of the glycated Hemoglobin (% hemoglobin A1c) in capillary whole blood obtained from the fingertip. The results from this assay are intended to be used for the monitoring of long-term blood glucose/metabolic control in individuals with diabetes mellitus.
Measurement Range	4.0-15.0 %	4.0-14.0%
Test Principle	Automated boronate affinity assay.	Latex enhanced turbidimetric immunoassay.
Type of Test	Quantitative in-vitro diagnostic test	Same
Intended Users	Prescription use. Waived users.	Same
Blood Sampling	Standard phlebotomy techniques for obtaining venous blood samples. Fingerstick by use of lancet.	For use only with capillary Fingerstick whole blood
Procedure for Filling of Sampling Device	Touch the surface or bring the tip of the capillary just beneath the surface of the blood drop/sample. Do not wipe off the capillary after filling	Same
Sample Volume	1.5 µL	Same
Capillary Material	Plastic	Glass
Cartridge Barcode	For analyzer identification of HbA1c test with capillary sampling device	Same
Package Insert and Quick Guide	Illustrations of cartridge and sampling device with plastic capillary.	Illustrations of cartridge and sampling device with glass capillary

Substantial Equivalence

The results obtained from the nonclinical and clinical evaluations confirmed the accuracy of the Nova Allegro Analyzer and Nova Allegro HbA1c Assay when used in the health care settings outlined in its intended use.

The Nova Allegro Analyzer and Nova Allegro HbA1c Assay displayed substantial equivalence to the legally marketed predicate device, Alere Afinion HbA1c Assay on the Afinion 2 Analyzer (K171650).