September 27, 2023

Abbott Diagnostics Technologies AS
Nathifa Bradshaw
Director Regulatory Affairs
Kjelsasveien 161
NO-0884 Oslo
Norway

Re: K214117
Trade/Device Name: Afinion™ HbA1c, Afinion™ 2, Alere Afinion™AS100 Analyzer
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated Hemoglobin Assay
Regulatory Class: Class II
Product Code: LCP, JQT
Dated: May 3, 2023
Received: May 3, 2023

Dear Nathifa Bradshaw:

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 (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 located 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.

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

803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214117

Device Name
Afinion™ HbA1c, Afinion™ 2 and Alere Afinion™ AS100 Analyzer

Indications for Use *(Describe)*

Afinion™ HbA1c

Afinion™ HbA1c is an in vitro diagnostic test for quantitative determination of glycated hemoglobin (% hemoglobin A1c, HbA1c) in venous and capillary human whole blood. The measurement of % HbA1c is recommended as a marker of long-term metabolic control in persons with diabetes mellitus.

Afinion™ 2

Afinion™ 2 analyzer is a compact multi-assay analyzer for point-of-care testing, designed to analyze the Afinion™ test cartridges. Afinion™ 2 system, consisting of Afinion™ 2 analyzer and Afinion™ test cartridges is for in vitro diagnostic use only.

Alere Afinion™ AS100 Analyzer

Alere Afinion™ AS100 Analyzer with Alere Afinion™ Data Connectivity Converter (ADCC) is a compact multi-assay analyzer for point-of-care testing, designed to analyze the Afinion™ Test Cartridges. The ADCC is a small device for automatic transfer of data, including patient and control assay results, from the Alere Afinion™ Analyzer to a laboratory information system or another electronic journal system.

Alere Afinion™ AS100 Analyzer System, consisting of Alere Afinion™ AS100 Analyzer with Alere Afinion™ Data Connectivity Converter (ADCC), Afinion™ Test Cartridges and Afinion™ Controls is for in vitro diagnostic use only.

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

GENERAL INFORMATION

Document# : k214117 & CW210007

Type of 510(k) : Dual Submission – 510(k) and CLIA waiver

Applicant Name: Abbott Diagnostics Technologies AS
Kjelsaasveien 161
PO Box 6863 Rodeloekka
NO-0504 Oslo
Norway
Establishment #9613069

Company Contact: Nathifa Bradshaw
Regulatory Affairs Manager
Phone: +1-561-428-2203
Email: nathifa.bradshaw@abbott.com

Date Prepared: September 26, 2023

DEVICE IDENTIFICATION

Trade or Proprietary Names:
Afinion™ HbA1c, Afinion™ 2 and Alere Afinion™ AS100 Analyzer

Common Name:
HbA1c test

Classification:

Product Code	Classification	Regulation Section	Classification Panel
LCP	Class II	21 CFR 864.7470	Hematology
JQT	Class I	21 CFR 862.2400	Chemistry

Predicate Device:

Afinion™ HbA1c (k171650) with Afinion™ 2 and Alere Afinion™ HbA1c (k151809) with Alere Afinion™ AS100 Analyzer.

The following are the legally marketed devices covered under the predicate device clearances, k171650 and k151809, and prior clearances:

The original Alere Afinion™ HbA1c assay and Afinion™ HbA1c Controls for use on the Afinion™ AS100 Analyzer were cleared under premarket notification k050574.

A modification to the Afinion™ HbA1c assay with the Afinion™ AS100 analyzer to add a new accessory, the Afinion™ Data Connectivity Converter, was cleared under k110056.

A modification to Afinion™ HbA1c assay with the Afinion™ AS100 analyzer was cleared under k151809.

A modification to the Afinion™ HbA1c assay with HbA1c Controls to include use with the Afinion™ 2 Analyzer was cleared under k171650.

DEVICE DESCRIPTION

The 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 Afinion™ HbA1c assay is designed to be used with the Afinion™ AS100 Analyzer and the Afinion™ 2 analyzer which are compact multi-assay analyzers for point-of-care testing. Quality control using the Afinion™ HbA1c Control is recommended to confirm that the system is working properly and provides reliable results.

INTENDED USE/INDICATIONS FOR USE

Afinion™ HbA1c

Afinion™ HbA1c is an *in vitro* diagnostic test for quantitative determination of glycated hemoglobin (% hemoglobin A1c, HbA1c) in venous and capillary human whole blood. The measurement of % HbA1c is recommended as a marker of long-term metabolic control in persons with diabetes mellitus.

Afinion™ 2
Afinion™ 2 analyzer is a compact multi-assay analyzer for point-of-care testing, designed to analyze the Afinion™ test cartridges. Afinion™ 2 system, consisting of Afinion™ 2 analyzer and Afinion™ test cartridges is for *in vitro* diagnostic use only.

Alere Afinion™ AS100 Analyzer

Alere Afinion™ AS100 Analyzer with Alere Afinion™ Data Connectivity Converter (ADCC) is a compact multi-assay analyzer for point-of-care testing, designed to analyze the Afinion™ Test Cartridges. The ADCC is a small device for automatic transfer of data, including patient and control assay results, from the Alere Afinion™ Analyzer to a laboratory information system or another electronic journal system.
Alere Afinion™ AS100 Analyzer System, consisting of Alere Afinion™ AS100 Analyzer with Alere Afinion™ Data Connectivity Converter (ADCC), Afinion™ Test Cartridges and Afinion™ Controls is for *in vitro* diagnostic use only.

COMPARISON WITH PREDICATE

Attribute	Predicate Device - k171650 Afinion™ HbA1c	Predicate Device-K151809 Alere Afinion™HbA1c	Candidate Device Modified Afinion™ HbA1c
Similarities			
Intended use	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.	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	Afinion™ HbA1c is an *in vitro* diagnostic test for quantitative determination of glycated hemoglobin (% hemoglobin A1c, % HbA1c) in venous and capillary human whole blood. The measurement of % HbA1c is recommended as a marker of long term metabolic control in persons with diabetes mellitus.
Assay principle	Afinion™ HbA1c is a fully automated boronate affinity assay for the determination of the percentage of hemoglobin A1c in human whole blood.	Same	Same
Blood samples	Venous whole blood and capillary fingerstick	Same	Same
Analyzer	Afinion™ 2	Alere Afinion™ AS100 Analyzer	Alere Afinion™ AS100 Analyzer and Afinion™ 2
User Interface	User display and operating instructions in labeling	Same	Same

Attribute	Predicate Device - k171650 Afinion™ HbA1c	Predicate Device-K151809 Alere Afinion™HbA1c	Candidate Device Modified Afinion™ HbA1c
Differences			
Test Procedure	**IMPORTANT!** • Do not use test cartridges that have been accidentally dropped on the floor or lab bench after specimen collection.	**IMPORTANT!** • Do not use test cartridges that have been accidentally dropped on the floor or lab bench after specimen collection.	• Addition to warning and precautions • Alterations in the presentation of the test result reporting • Text update to align with American Diabetes Association (ADA) recommendations • Inclusion of a performance characteristics disclaimer • Revisions to bibliography page **IMPORTANT!** • Do not use test cartridges that have been accidentally dropped on the floor or lab bench after sample collection. • Do not use cold test cartridges. • Use the test cartridge within 10 minutes after opening the foil pouch.

Attribute	Predicate Device - k171650 Afinion™ HbA1c	Predicate Device-K151809 Alere Afinion™HbA1c	Candidate Device Modified Afinion™ HbA1c
Analytical specificity	The following hemoglobin (Hb) variants have been analyzed and found not to affect the Alere Afinion™ HbA1c test result: HbAC, HbAD, HbAE, HbF, HbAJ and HbAS. Carbamylated hemoglobin does not affect the Alere Afinion™ HbA1c test result. Pre-glycated hemoglobin does not affect the Alere Afinion™ HbA1c result.	The following hemoglobin (Hb) variants have been analyzed and found not to affect the Alere Afinion™ HbA1c test result: HbAC, HbAD, HbAE, HbF, HbAJ and HbAS. Carbamylated hemoglobin does not affect the Alere Afinion™ HbA1c test result. Pre-glycated hemoglobin does not affect the Alere Afinion™ HbA1c result.	No significant interference (≤ 7%) was observed for samples with hemoglobin (Hb) variants and hemoglobin derivatives up to the following concentrations: • HbA2 5.7 % • HbAC 36 % • HbAD 42 % • HbAE 26 % • HbAS 42 % • HbF 10.4 % • Acetylated Hb 4.6 mg/mL • Carbamylated Hb 13.8 mg/mL • Labile (pre-glycated) Hb 11.4 mg/mL
Limitations	No HbF limitation	No HbF limitation	The highest HbF concentration where no significant interference (≤ 7%) is observed is 10.4% HbF. Above 10.4% HbF, a negative interference is observed.
Limitations	Do not analyze hemolyzed or coagulated samples.	Do not analyze hemolyzed or coagulated samples.	Coagulated or hemolyzed samples cannot be used with Afinion™ HbA1c. Samples with >14% (2000 mg/dL) hemolysis may return an information code.

Interference	No significant interference (<5%) was observed up to the following concentrations: • Bilirubin - 342 µmol/L (20 mg/dL) • Triglycerides - 15.7 mmol/L (1389 mg/dL) • Cholesterol - 9.1 mmol/L (351 mg/dL) • Glucose - 27.8 mmol/L (500 mg/dL) • Fructosamine - 680 µmol/L • Hemolysis - 5.0% • Anticoagulants (EDTA, heparin and citrate) at concentrations normally used in blood collection tubes. • Acetaminophen - 1.7 mmol/L (256 µg/mL) • Ibuprofen - 1.8 mmol/L (372 µg/mL) • Acetylsalicylic acid - 3.3 mmol/L (599 µg/mL) • Salicylic acid - 4.3 mmol/L (593 µg/mL) • Glyburide - 3.9 µmol/L • Metformin - 310 µmol/L	No significant interference (<5%) was observed up to the following concentrations: • Bilirubin - 342 µmol/L (20 mg/dL) • Triglycerides - 15.7 mmol/L (1389 mg/dL) • Cholesterol - 9.1 mmol/L (351 mg/dL) • Glucose - 27.8 mmol/L (500 mg/dL) • Fructosamine - 680 µmol/L • Hemolysis - 5.0% • Anticoagulants (EDTA, heparin and citrate) at concentrations normally used in blood collection tubes. • Acetaminophen - 1.7 mmol/L (256 µg/mL) • Ibuprofen - 1.8 mmol/L (372 µg/mL) • Acetylsalicylic acid - 3.3 mmol/L (599 µg/mL) • Salicylic acid - 4.3 mmol/L (593 µg/mL) • Glyburide - 3.9 µmol/L • Metformin - 310 µmol/L	No significant interference (≤7%) was observed up to the following concentrations: • Bilirubin conjugated 600 mg/L • Bilirubin unconjugated 600 mg/L • Glucose 10 g/L • Lipids (as Intralipid) 10 g/L • Rheumatoid factor 780 000 IU/L • Total protein 15 g/dL • Glycated albumin 7.7 g/L • Acetaminophen 200 mg/L • Acetylcysteine 1663 mg/L • Acetylsalicylic acid 1000 mg/L • Ampicillin 1000 mg/L • Ascorbic acid 300 mg/L • Cefoxitin 2500 mg/L • Cyclosporine A 5 mg/L • Cyclosporine C 5 mg/L • Doxycycline 50 mg/L • Glyburide 1.9 mg/L • Heparin 5000 U/L • Ibuprofen 500 mg/L • Levodopa 20 mg/L • Metformin 40 mg/L • Methyldopa 20 mg/L • Metronidazole 200 mg/L • Phenylbutazone 400 mg/L • Rifampicin 64 mg/L • Salicylic acid 599 mg/L • Theophylline 100 mg/L • Hemolysis (*in vitro*) 14 % • Anticoagulants (EDTA, heparin and citrate) at concentrations normally used in blood collection tubes do not interfere.

DESCRIPTION OF DEVICE MODIFICATION

The Afinion™ HbA1c assay labeling was modified to incorporate information from the previously cleared diagnostic version of the test – Afinion™ HbA1c Dx. Supporting data included information on analytical specificity for hemolysis, hemoglobin derivatives, hemoglobin variants and, exogenous and endogenous substances.

CONCLUSION

The information and data in this 510(k) application demonstrate that the Afinion™ HbA1c assay with modified labeling is substantially equivalent to the unmodified predicate devices.