November 29, 2018

Alere Technologies AS
Monica Vallestad
Regulatory Affairs Manager
Kjelsaasveien 161
Oslo, NO-0884
Norway

Re: K182988
Trade/Device Name: Afinion HbA1c Dx on Afinion 2
Regulation Number: 21 CFR 862.1373
Regulation Name: Hemoglobin A1c test system
Regulatory Class: Class II
Product Code: PDJ, JQT
Dated: October 26, 2018
Received: October 29, 2018

Dear Monica Vallestad:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k182988

Device Name
Afinion HbA1c Dx on Afinion 2

Indications for Use *(Describe)*
Afinion™ HbA1c Dx is an in vitro diagnostic test for quantitative determination of glycated hemoglobin (% hemoglobin A1c, HbA1c) in human venous and capillary whole blood.
This test is to be used as an aid in the diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabetes.
The measurement of % HbA1c is recommended as a marker of long-term metabolic control in persons with diabetes mellitus.

The Afinion™ 2 System consisting of the Afinion™ 2 Analyser and the Afinion™ Test Cartridges is for in vitro diagnostic use only. The Afinion™ 2 Analyzer is a compact multi-assay analyzer for point-of-care testing and is designed to analyze the Afinion™ 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 k182988

GENERAL INFORMATION

Applicant Name: Alere Technologies AS
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NO-0504 Oslo
Norway
Establishment #9613069

Company Contact: Monica Vallestad
Regulatory Affairs manager
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Email: monica.vallestad@alere.com

Date Prepared: November 28, 2018

DEVICE IDENTIFICATION

Trade or Proprietary Names:
Afinion™ HbA1c Dx on Afinion™ 2

Common Name:
HbA1c test
Analyzer

Classification:

Product Code	Classification	Regulation Section	Classification Panel
PDJ	Class II	21 CFR 862.1373	Hematology
JQT	Class I	21 CFR 862.2400	Chemistry

Predicate Device: Afinion™ HbA1c Dx on Alere Afinion™ AS100 Analyzer (k180296)

The following are the legally marketed devices covered under the predicate device clearance, k180296, and their prior clearances:

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

The Alere Afinion™ ACR assay with ACR controls for use with the Alere Afinion™ AS100 Analyzer was cleared under k072409.

The system, including both HbA1c and ACR assays and the Afinion AS100 Analyzer, was cleared under k110056 for the addition of a new accessory, the Afinion Data Connectivity Converter.

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

The Alere Afinion™ ACR assay with ACR controls for use with the Afinion™ AS100 Analyzer was cleared under k171650.

HbA1c Dx for use with Alere Afinion™ AS100 Analyzer was cleared under k180296

DEVICE DESCRIPTION

The Afinion™ HbA1c Dx test system is a CLIA moderate complexity test for diagnosing diabetes and identifying patients who may be at risk for developing diabetes, as a marker of long-term metabolic control in persons with diabetes mellitus.

The Afinion 2 is a multi-assay analyzer for point-of-care testing, designed for use with Afinion assay test cartridges and Afinion controls. It has the same functionality as the Afinion AS100 analyzer performing identical assay processing.

INTENDED USE/INDICATIONS FOR USE

Afinion™ HbA1c Dx is an *in vitro* diagnostic test for quantitative determination of glycated hemoglobin (% hemoglobin A1c, HbA1c) in human venous and capillary whole blood.

This test is to be used as an aid in the diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabetes.

The measurement of % HbA1c is recommended as a marker of long-term metabolic control in persons with diabetes mellitus.

The Afinion™ 2 system, consisting of Afinion™ 2 analyzer and the Afinion™ test cartridges is for *in vitro* diagnostic use only. The Afinion™ 2 Analyzer is a compact

multi-assay analyzer for point-of-care testing and is designed to analyze the Afinion™ Test Cartridges.

COMPARISON WITH PREDICATE

Attribute	Predicate Device - k180296 Afinion HbA1c Dx with Afinion AS100 Analyzer	Candidate Device Afinion HbA1c Dx with Afinion 2 analyzer
Similarities		
Intended use	Afinion™ HbA1c Dx 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.	Same
Assay principle	Afinion HbA1c Dx is a fully automated boronate affinity assay for the determination of the percentage of hemoglobin A1c in human whole blood.	Same
Standardization	Afinion HbA1c Dx is traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Reference Method for Measurement of HbA1c. HbA1c values are reported according to the NGSP recommendations at DCCT (Diabetes Control and Complications Trial) level. Afinion HbA1c Dx is certified by NGSP.	Same
Analyzer function	Assay cartridge processing including pumping, heating, image processing	Same
Cartridge interface	Physical processing of cartridge (locking, docking, splitting, foil penetration, merging)	Same
User Interface	User display and operating instructions in labeling	Same

Differences		
Instrument components	Most components in metal	Several metal components replaced with injection molded plastics with more sub-assemblies
Electronics	Obsolete components or components that will be obsolete in near future, e.g. CPU and memory 14 PCBs in use	Obsolete components replaced by those with more current technology 9 PCBs in use
Dimensions	190 mm W x 170 mm H x 340 mm D 5 kg	200 mm W x 186 mm H x 328 mm D 3.4 kg
Connectivity	Separate connectivity unit with Ethernet plug	Ethernet plug incorporated into the analyzer and connectivity software incorporated in the software

DESCRIPTION OF DEVICE MODIFICATION

The Afinion 2 analyzer is a modification of the cleared Afinion AS100 analyzer for use with Afinion assays with no change in intended use. The Afinion™ 2 analyzer has the same functionality and user interface as the Alere Afinion™ AS100 Analyzer. The primary modifications are changes in component materials and other minor changes in component design in order to make a more robust analyzer. Software, overall architecture and high-level requirements remain unchanged from the Alere Afinion™ AS 100 Analyzer to the Afinion™ 2 Analyzer. Software design in the Afinion™ 2 Analyzer was modified from the Alere Afinion™ AS 100 Analyzer wherever needed to adapt to changes made to electronics and mechanics to maintain assay sequence timing as in the Alere Afinion™ AS100 Analyzer.

DESIGN CONTROL ACTIVITIES

The design development and verification/validation of the device modification have been performed under design control. The design control activities were based on risk analysis, and acceptance criteria were set to maintain the performance and safety of the Afinion™ system using the applicable Afinion™ tests with the device.

All requirements for Alere Afinion™ AS100 Analyzer have been re-verified for Afinion™ 2 analyzer through tests both at system level and discipline level (electronics, mechanics and software).

The risk analysis identified the appropriate in-house analytical performance verification studies to demonstrate that the analytical performance and risk of erroneous results for Afinion™ HbA1c Dx are not adversely affected by using the modified device.

CONCLUSION

Verification and validation studies were performed as required by risk analysis and all acceptance criteria were met. The Afinion HbA1c Dx on the Afinion 2 is found to be substantially equivalent to the predicate device, Afinion HbA1c Dx on the Alere Afinion AS100.