



Food and Drug Administration
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September 25, 2015

ALERE TECHNOLOGIES AS
KARI SKINNEMOEN
REGULATORY AFFAIRS MANAGER
KJELSAASVEIEN 161
OSLO, NO NO-0884

Re: K151809

Trade/Device Name: Alere Afinion Hba1c and Alere Afinion AS100 Analyzer

Regulation Number: 21 CFR 864.7470

Regulation Name: Glycosylated Hemoglobin Assay

Regulatory Class: II

Product Code: LCP, JQT

Dated: June 26, 2015

Received: July 2, 2015

Dear Dr. Skinnemoen:

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Katherine Serrano -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

Indications for Use

510(k) Number (if known)
k151809

Device Name
Alere Afinion HbA1c and Alere Afinion™AS100 Analyzer

Indications for Use (Describe)

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), Alere Afinion™ Test Cartridges and Alere Afinion™ Controls is for in vitro diagnostic use only.

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.

Alere Afinion™HbA1c Controls have been designed for use with the Alere Afinion™AS100 Analyzer System. Quality control using the Alere Afinion™HbA1c Control should be done to confirm that the Alere Afinion™AS100 Analyzer System is working properly and provides reliable result.

The Alere Afinion™ ACR assay is an in vitro diagnostic test for quantitative determination of albumin, creatinine and albumin/creatinine ratio (ACR) in human urine using the Alere Afinion™ AS100 Analyzer. The measurement of urine albumin, creatinine and albumin/creatinine ratio, aids in the early diagnosis of nephropathy.

The Alere Afinion™ ACR Control kit contains liquid preparations of albumin and creatinine in citrate buffer. The controls should be used to confirm that the Alere Afinion™AS100 Analyzer System is working properly and provides reliable results.

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

This summary of 510(k) safety and efficacy information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **k151809**

Submission type: Special 510(k)

Submitter/Owner: Alere Technologies AS
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Contact person: Ms. Kari Skinnemoen, Regulatory Affairs Manager
E-mail: kari.skinnemoen@alere.com

Preparation date: 24 June 2015

Device Name: Alere Afinion™ HbA1c and Alere Afinion™ AS100 Analyzer

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

Predicate Devices:

The predicate devices are the following legally marketed devices:

Alere Afinion™ HbA1c and Alere Afinion™ AS100 Analyzer

The Alere Afinion™ HbA1c test system consists of the Alere Afinion™ AS100 Analyzer and the Alere Afinion HbA1c test cartridge. The system was initially cleared under Pre-Market Notification k050574 and later cleared under Pre-Market Notification k110056. The test is waived under the Clinical Laboratory Improvement Amendment of 1988 (CLIA '88) for current indications for use (CR140337).

Alere Afinion™ AS100 Analyzer is cleared under k110056 also for use with other analyte assay and controls, which are not affected by this modification: Alere Afinion™ ACR, Alere Afinion™ HbA1c Control and Alere Afinion™ ACR Control.

Alere Afinion™ Lipid Panel and Alere Afinion™ Lipid Panel Control are cleared under k132031 for use with Alere Afinion™ AS100 Analyzer.

Intended use/Indications for use (k110056)

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), Alere Afinion™ Test Cartridges and Alere Afinion™ Controls is for in vitro diagnostic use only.

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.

Alere Afinion™ HbA1c Controls have been designed for use with the Alere Afinion™ AS100 Analyzer System. Quality control using the Alere Afinion™ HbA1c Control should be done to confirm that the Alere Afinion™ AS100 Analyzer System is working properly and provides reliable result.

The Alere Afinion™ ACR assay is an in vitro diagnostic test for quantitative determination of albumin, creatinine and albumin/creatinine ratio (ACR) in human urine using the Alere Afinion™ AS100 Analyzer. The measurement of urine albumin, creatinine and albumin/creatinine ratio, aids in the early diagnosis of nephropathy.

The Alere Afinion™ ACR Control kit contains liquid preparations of albumin and creatinine in citrate buffer. The controls should be used to confirm that the Alere Afinion™ AS100 Analyzer System is working properly and provides reliable results.

Intended use/Indications for use (k132031)

The Afinion™ Lipid Panel is an *in vitro* diagnostic test for quantitative determination of total cholesterol (Chol), high-density lipoprotein (HDL) cholesterol and triglycerides (Trig) in serum. Values for low-density lipoprotein (LDL) cholesterol, non-HDL cholesterol and Chol/HDL ratio are calculated by the Afinion™ AS100 Analyzer. Chol, HDL cholesterol, Trig, and calculated LDL cholesterol, non-HDL cholesterol and Chol/HDL ratio) are used in the diagnosis and treatment of disorders involving excess or low cholesterol in the blood and lipid and lipoprotein metabolism disorders.

Afinion™ Lipid Panel Control has been designed for use with the Afinion™ AS100 Analyzer and Afinion™ Lipid Panel. Afinion™ Lipid Panel Control is intended for use as assayed control material for total cholesterol (Chol), high-density lipoprotein (HDL) cholesterol and triglycerides (Trig). The controls should be used to confirm that the Afinion™ AS100 Analyzer System is working properly and provides reliable results.

For use in clinical laboratories and point of care laboratory settings.

For prescription use only.

Principle of the assay

Alere Afinion™ HbA1c

The Alere Afinion HbA1c test cartridge contains all of the reagents necessary for the determination of % HbA1c. The sample material is collected from a fingerstick or a sample tube with the integrated sampling device before the test cartridge is placed in the cartridge chamber of the Alere Afinion AS100 Analyzer. The blood sample is then automatically diluted and mixed with a solution that releases hemoglobin from the erythrocytes. The hemoglobin precipitates. This sample mixture is transferred to a blue boronic acid conjugate, which binds to the cis-diols of glycated hemoglobin. This reaction mixture is soaked through a filter membrane and all precipitated hemoglobin, conjugate-bound and unbound (i.e. glycated and non-glycated hemoglobin) remains on the membrane. Any excess of conjugate is removed with a washing reagent. The analyzer evaluates the precipitate on the membrane. By measuring the reflectance, the blue (glycated hemoglobin) and the red (total hemoglobin) color intensities are evaluated, the ratio between them of which is proportional to the percentage of HbA1c in the sample. The % HbA1c is displayed on the Alere Afinion™ AS100 Analyzer.

Alere Afinion™ AS100 Analyzer

The analyzer uses different chemical and mechanical assay methods combined with advanced, computerized processing and measuring technology to perform a variety of diagnostic assays.

A test cartridge with patient sample or control is placed in the cartridge chamber of the analyzer. By manually closing the lid, the test cartridge is transported into the analysis compartment of the analyzer. There is no further user intervention or activity required to perform the assay. Test and lot specific information are obtained from the test cartridge barcode label, which then initiates the processing of the test. The sample and reagents are automatically transferred between the wells of the test cartridge.

A monochrome solid-state camera monitors the entire process. When the assay is completed, light-emitting diodes (LEDs) illuminate the final reaction area, which can be either a colored membrane or a reaction well. The camera detects the reflected or transmitted light, which is converted to a test result and displayed on the touch screen. When the user accepts the result, the lid covering the cartridge chamber opens automatically and the used test cartridge can be removed and discarded. The analyzer is then ready for the next run.

Description of Device Modification

The current sampling device integrated in the test cartridge is made of plastic with a glass capillary tube glued into the sampling device. The new, modified plastic sampling device will be manufactured in one piece of plastic of the same base material (polystyrene) as the plastic part of the current sampling device.

Comparison Information

The design and appearance of the plastic sampling device will be very similar to the current sampling device and the user handling will be the same as for the current sampling device.

Similarities		
Attribute	Alere Afinion HbA1c system (predicate)	Modified device
Intended use	Measurement of %HbA1c in human whole blood as a marker of long term metabolic control in persons with diabetes mellitus.	Same
Test principle	Automated boronate affinity assay.	Same
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.	Same
Procedure for filling of sampling device capillary	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
Fill volume of sampling device capillary	1.5 µL	Same
Design of sampling device	Grip for pulling up and inserting the sampling device into the cartridge	Same

Differences		
Attribute	Alere Afinion HbA1c system (predicate)	Modified device
Sampling device capillary material and appearance	Glass	Plastic Slightly different shape and appearance.
Cartridge barcode	For analyzer identification of HbA1c test with glass capillary sampling device.	For analyzer identification of HbA1c test with plastic capillary sampling device
Package Insert and Quick Guide	Illustrations of cartridge and sampling device with glass capillary.	Illustrations of cartridge and sampling device with plastic capillary.

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 efficiency and safety of the assay in the hands of waived users. The verification/validation program included in-house studies of precision, accuracy, robustness and potential interference of plastic additive as well as external waived user studies.

Conclusion

As required by the risk analysis, all verification and validation activities were performed and the results demonstrated that the predetermined acceptance criteria were met. The modified devices are substantially equivalent to the predicate devices.