November 21, 2017

Abbott Rapid Diagnostics
Annie Wright
Senior Regulatory Affairs Manager
9975 Summers Ridge Road
San Diego, California 92121

Re: K171650
Trade/Device Name: Alere Afinion™ HbA1c and ACR on Afinion™ 2 analyzer
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP, JFY, JQT
Dated: June 2, 2017
Received: June 5, 2017

Dear Annie Wright:

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 Part 801 and Part 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.

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.

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,

Courtney H. Lias -S

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)*
K171650

Device Name
Alere Afinion™ HbA1c and ACR on Afinion™ 2 analyzer

Indications for Use *(Describe)*
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 Alere Afinion™ test cartridges 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.
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 Afinion™ 2 analyzer. The measurement of urine albumin, creatinine and albumin/creatinine ratio, aids in the early diagnosis of nephropathy.

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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K171650 510(k) SUMMARY

GENERAL INFORMATION

Submitter: Abbott Rapid Diagnostics
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Annie Wright
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Phone: (858) 805-2316
Email: annie.wright@alere.com

Applicant Name: Abbott Rapid Diagnostics
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PO Box 6863 Rodeloekka
NO-0504 Oslo
Norway
Establishment #9613069

Date Prepared: November 20, 2017

DEVICE IDENTIFICATION

Trade or Proprietary Names:

- Alere Afinion™ HbA1c
- Alere Afinion™ ACR
- Afinion™ 2

Common Name:

- HbA1c test
- ACR test
- Analyzer

Classification:

Product Code	Classification	Regulation Section	Classification Panel
LCP	Class II	21 CFR 864.7470	Hematology
JFY	Class II	21 CFR 862.1225	Chemistry
JQT	Class I	21 CFR 862.2400	Chemistry

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Predicate Device: Alere Afinion™ HbA1c and Alere Afinion™ AS100 Analyzer (k151809)

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

The Alere Afinion™ HbA1c assay with HbA1c controls for use with the Alere Afinion™ AS100 Analyzer was cleared under k050574.
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.

DEVICE DESCRIPTION

The Afinion™ 2 analyzer is a multi-assay analyzer for point-of-care testing, designed for use with Alere Afinion™ assays. The Afinion™ 2 analyzer is a modification, a new model, of the previously cleared device Alere Afinion™ AS100 Analyzer.

INTENDED USE/INDICATIONS FOR 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.

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 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 Afinion™ 2 analyzer. The measurement of urine albumin, creatinine and albumin/creatinine ratio, aids in the early diagnosis of nephropathy.

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COMPARISON WITH PREDICATE

Attribute	Predicate Device Alere Afinion™ AS100 Analyzer k151809	Candidate Device Alere Afinion™ HbA1c and ACR on Afinion™ 2 analyzer
Similarities		
Intended use	Alere Afinion™ 2 is a compact multi-assay analyzer for point-of-care testing, designed to analyze the Afinion™ test cartridges.	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
Peripheral units	A barcode reader and printer can be connected	Same
Differences		
Components	Most components in metal	Several metal components replaced with injection molded plastics
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 Alere Afinion™ HbA1c and ACR on Afinion™ 2 analyzer has the same functionality and user interface as the Alere Afinion™ AS100 Analyzer. The intended use/indications for use and fundamental scientific technology have not changed. The primary modifications are changes in component materials and other minor changes in component design in order to make a more robust analyzer. Electronic components that

are obsolete or expected to become obsolete in the near future were changed. 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 in order to maintain assay sequence timing as it is 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 Alere 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 Alere Afinion™ HbA1c and Alere Afinion™ ACR 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. This device is found to be substantially equivalent to the predicate device.