Alere Scarborough, Inc. August 8, 2018
Angela Drysdale
VP, Regulatory Affairs – Infectious Disease
10 Southgate Road
Scarborough, ME 04074

Re: K181853
Trade/Device Name: Alere BinaxNOW Influenza A & B Card 2, Alere Reader
Regulation Number: 21 CFR 866.3328
Regulation Name: Influenza virus antigen detection test system
Regulatory Class: Class II
Product Code: PSZ
Dated: July 10, 2018
Received: July 11, 2018

Dear Angela Drysdale:

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,

Tamara V. Feldblyum -S for

Uwe Scherf, Ph.D.
Director
Division of Microbiology 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K181853

Device Name
Alere BinaxNOW Influenza A & B Card 2 and Alere Reader

Indications for Use *(Describe)*
The Alere BinaxNOW Influenza A & B Card 2 is an i*n vitro* immunochromatographic assay for the qualitative detection of influenza A and B nucleoprotein antigens in nasopharyngeal (NP) swab and nasal swab specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. Negative test results are presumptive and should be confirmed by cell culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. Alere BinaxNOW Influenza A & B Card 2 must be read by the Alere Reader.

Performance characteristics for influenza A were established during the 2015-2016 influenza season when influenza A/H3N2 and A/H1N1 pandemic were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

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

The assigned 510(k) number is: K181853

SUBMITTER

Alere Scarborough, Inc.
10 Southgate Road
Scarborough, ME 04074
Establishment Registration Number: 1221359

CONTACT PERSON

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Angela.drysdale@alere.com (email)

DATE PREPARED

7/10/2018

TRADE NAME

Alere BinaxNOW® Influenza A & B Card 2
Alere™ Reader

COMMON NAME

BinaxNOW® Influenza A & B Card 2, BinaxNOW® Card 2, Alere Influenza A & B 2, BinaxNOW® Flu Card 2/Reader, Lateral Flow Reader, Card Test Analyzer

CLASSIFICATION NAME

Influenza virus antigen detection test system (per 21 CFR 866.3328)

CLASSIFICATION

Class II

PRODUCT CODE

PSZ

PANEL

Microbiology (83)

PREDICATE DEVICE

Alere BinaxNOW® Influenza A & B Card 2 and Alere™ Reader, K173502

DEVICE DESCRIPTION

The Alere BinaxNOW® Influenza A & B Card 2 is an immunochromatographic membrane assay that detects influenza type A and B nucleoprotein antigens in respiratory specimens. Influenza specific antibodies and a control antibody are immobilized onto a membrane support as three distinct lines and combined with other reagents/pads to construct a test strip. The test strip is mounted inside a cardboard, book-shaped hinged test card.

Swab specimens require a sample preparation step, in which the sample is eluted off the swab into Elution Solution. Sample is added to the top of the test strip and the test card is closed. Test results are interpreted at 15 minutes based on the presence or absence of Sample Lines. Alere BinaxNOW® Influenza A & B Card 2 test results must be read by the Alere™ Reader.

The Alere™ Reader is an easy to use bench top instrument that can be used near patient and in laboratory settings which will interpret, capture and transmit test results. The Alere™ Reader is a camera based instrument that detects the presence and identity of the Alere BinaxNOW® Influenza A& B Card 2 assay, analyzes the intensity of the test and control lines and displays the results (positive, negative or invalid) on a display screen. The screen is intended as a means of user interface informing the user how to operate the Reader and to display test results, including any errors. Data can be retrieved and downloaded by the operator at any time after testing and uploaded to the hospital LIS/LIM system, if desired. Operator ID and Subject ID can be entered manually or via the provided barcode scanner. An external printer can be attached via USB to the Alere™ Reader to print test results.

INTENDED USE

The Alere BinaxNOW® Influenza A & B Card 2 is an *in vitro* immunochromatographic assay for the qualitative detection of influenza A and B nucleoprotein antigens in nasopharyngeal (NP) swab and nasal swab specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. Negative test results are presumptive and should be confirmed by cell culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. Alere BinaxNOW® Influenza A & B Card 2 must be read by the Alere™ Reader.

Performance characteristics for influenza A were established during the 2015-2016 influenza season when influenza A/H3N2 and A/H1N1 pandemic were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

COMPARISON TO THE PREDICATE

The purpose of this Special 510k submission is to bring to market a modification of the software contained on the Alere™ Reader. There have been no changes to the Alere BinaxNOW® Influenza A & B Card 2 test. A modification of the Alere™ Reader algorithm was made to mitigate a low frequency failure mode where the Alere™ Reader detects a partial line or dark spot within the test line and may call the test result positive, resulting in a false positive result. In addition to the algorithm modification, the modified software incorporates additional updates and enhancements to the Alere™ Reader.

Alere BinaxNOW® Influenza A & B Card 2 incorporating the software modification was compared to the legally marketed predicate device, the 510(k) cleared Alere BinaxNOW® Influenza A & B Card 2 test.

Parameter	**Alere BinaxNOW® Influenza A & B Card 2 (with software modification)**	**Alere BinaxNOW® Influenza A & B Card 2 (K173502)**
FDA Product Code	PSZ	Same
Assay Target	Influenza A, Influenza B	Same
Intended Use	The Alere BinaxNOW® Influenza A & B Card 2 is an *in vitro* immunochromatographic assay for the qualitative detection of influenza A and B nucleoprotein antigens in nasopharyngeal (NP) swab and nasal swab specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. Negative test results are presumptive and should be confirmed by cell culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. Alere BinaxNOW® Influenza A & B Card 2 must be read by the Alere™ Reader. Performance characteristics for influenza A were established during the 2015-2016 influenza season when influenza A/H3N2 and A/H1N1 pandemic were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary. If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be	Same

Parameter	Alere BinaxNOW® Influenza A & B Card 2 (with software modification)	Alere BinaxNOW® Influenza A & B Card 2 (K173502)
	collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.	
Intended Environment for Use	Professional use, in a medical laboratory or point of care (CW170003)	Same
Instrumentation	Alere™ Reader	Same
Assay Information		
Sample Type	Nasal and Nasopharyngeal Swab	Same
Internal Control	Yes	Same
Assay Result	Qualitative	Same
Time to Result	15 minutes	Same