SPECIAL 510(k): Device Modification
OIR Review Summary

To: Alere Scarborough, Inc. **RE:** K173502

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device:

Alere BinaxNOW Influenza A & B Card 2

510(k) number: K162642

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

3. Description of the device **MODIFICATION(S):**

A software modification has been added to allow the reader to operate in "Walk-away" mode. In walk-away mode, the operator inserts the test card into the reader instead of manually timing the test for the designated 15 minutes on the benchtop. The reader begins a 15 minute countdown and records the results at precisely 15 minutes after the test card was inserted. The test results are available when the operator returns to the reader. The reader mode (Read Now or Walk-away) is set by the administrator only. The Alere BinaxNOW Influenza A & B Card 2 assay package insert, Alere Reader user manual, and Quick Reference Instructions (QRI) have been updated to include the additional information.

4. The **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed.**

5. Comparison Information

A. Similarities

	Predicate Device	Modified Device
Features	Alere BinaxNOW Influenza A & B Card 2 (K162642)	Alere BinaxNOW Influenza A & B Card 2 (K173502)
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.	Same

	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.	
Sample Type	Nasopharyngeal and nasal swabs	Same
Assay Target	Nucleoprotein Antigen of Influenza A and B	Same
Instrumentation	Alere Reader	Same
Detection Format	The camera-based Reader detects the presence and identity of the Alere BinaxNOW Influenza A & B Card 2 assay, analyzes the intensity of the sample and control line and reports the results (positive, negative, or invalid) on a display screen.	Same
Internally Controlled?	Yes	Same
Assay Result	Qualitative	Same
Time to Result	15 minutes	Same

B. Differences

The assay package insert, Alere Reader user manual, and QRI have been updated to include instructions on the use of the new Walk-away mode.

6. Design Control Activities Summary:

A risk assessment of device modification was conducted and documented according to Alere Scarborough, Inc. Quality System requirements. The modification made to the assay does not affect the assay procedure, and this change was not expected to impact the performance of the test or its safety and effectiveness. To confirm assay performance was not negatively impacted, Alere Scarborough Inc. performed the following validation studies:

A. Opening Drawer Study
B. Device Timing Study
C. Walk Away Equivalency Study

Opening Drawer Study
The purpose of this study was to confirm that the Alere Reader Walk-away mode displays an error message when the test drawer is opened during the device read. Influenza A and B LoD QC controls were tested as positive samples. Elution solution was tested as the negative sample. With the reader in Walk-away mode, for each sample tested, the operator opened the drawer for five seconds and then closed the drawer again. Times tested for the drawer opening study were when the following amounts of time were remaining on the test: 10 minutes before, 5 minutes before, 3 seconds before, and 0 seconds (i.e., immediately before) the result is displayed on the screen. Correct results were obtained for each sample if the drawer was closed again prior to the expiration of the 15 minute reader timer (i.e. when the "read" was performed by the reader). For samples where the drawer was open when the Reader attempted to read the card, an invalid test result error message was presented to the user.

Device Timing Study
The purpose of this study was to evaluate the effect on performance if the Alere BinaxNOW Influenza A & B Card 2 is not inserted into the Alere Reader immediately after closing the card. Influenza A and B LoD QC controls or elution buffer were tested at n=20 replicates and inserted into the Alere Reader in Walk-away mode at the following times after closing of the card: 0 minutes (SOP), 5 minutes, 10 minutes, 15 minutes, or 30 minutes. The results were read at the completion of the reader time in Walk-away mode. All positive and negative swabs generated the expected results. Assay results do not appear to be affected if the test is delayed by as long as 30 minutes before starting the 15 minute Walk-away mode read method.

Equivalency Study
The purpose of this study was to confirm the Alere BinaxNOW Influenza A & B Card 2 test performance is equivalent when the tests are read by the Alere Reader in both Read Now and Walk-away mode. To perform this study, Influenza A and Influenza B LoD QC controls were tested with n=42 replicates per sample in Read Now and Walk-away mode. Elution buffer was used for negative samples. Expected results were obtained for all samples tested in both modes with exception to one false positive Influenza A result for an elution buffer sample. The false result was attributed to a discolorization of the nitrocellulose membrane being interpreted as a positive result by the reader. The sample was retested and the expected results were obtained. The results of this study demonstrate that the Alere BinaxNOW Influenza A & B Card 2 yields valid and expected results when the device is read by the Alere Reader using either Read Now or Walk-away mode.

7. **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure.**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared device.