



Food and Drug Administration
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ALERE SCARBOROUGH, INC.
ANGELA DRYSDALE
VP REGULATORY AFFAIRS - INFECTIOUS DISEASE
10 SOUTHGATE RD
SCARBOROUGH ME 04074

December 21, 2016

Re: K163266

Trade/Device Name: Alere i Influenza A & B, Alere i Influenza A & B Control Swab Kit,
Alere i Instrument

Regulation Number: 21 CFR 866.3980

Regulation Name: Respiratory viral panel multiplex nucleic acid assay

Regulatory Class: II

Product Code: OCC, OZE, OOI

Dated: November 18, 2016

Received: November 21, 2016

Dear Ms. 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. 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,

Himani Bisht -S
2016.12.21 14:36:55 -05'00'

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K163266

Device Name

Alere™ i Influenza A & B

Indications for Use (Describe)

The Alere™ i Influenza A & B assay performed on the Alere™ i Instrument is a rapid molecular *in vitro* diagnostic test utilizing an isothermal nucleic acid amplification technology for the qualitative detection and discrimination of influenza A and B viral RNA in direct nasal swabs and nasal or nasopharyngeal swabs eluted in viral transport media from patients with signs and symptoms of respiratory infection. It is intended for use as an aid in the differential diagnosis of influenza A and B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay is not intended to detect the presence of influenza C virus.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Performance characteristics for influenza A were established during the 2012-2013 and the 2014-2015 influenza seasons when influenza A/H3 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.

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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 SDMA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K163266

SUBMITTER

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CONTACT PERSON

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DATE PREPARED

11/18/2016

TRADE NAME

Alere™ i Influenza A & B

COMMON NAME

Alere™ i flu, Alere™ i, Alere™ Influenza A & B

CLASSIFICATION NAME

Respiratory Viral Panel Multiplex Nucleic Acid Assay (per 21 CFR 866.3980)
Instrumentation for Clinical Multiplex Test Systems (per 21 CFR 862.2570)

CLASSIFICATION

Class II

PRODUCT CODE

OCC, OZE, 001

PANEL

Microbiology (83)

PREDICATE DEVICES

Alere™ i Influenza A & B, K151464

DEVICE DESCRIPTION

Alere™ i Influenza A & B is a rapid, instrument-based isothermal tests for the qualitative detection and differentiation of influenza A and influenza B from nasal swabs and nasal or nasopharyngeal swabs eluted in viral transport media from patients presenting with signs and symptoms of respiratory infection. The Alere™ i Influenza A & B system utilizes isothermal nucleic acid amplification technology and is comprised of:

- Sample Receiver – single use, disposable containing the elution buffer
- Test Base – single use, disposable comprising two sealed reaction tubes, each containing a lyophilized pellet
- Transfer Cartridge – single use, disposable for transfer of the eluted sample to the Test Base, and
- **Alere™ i Instrument** – repeat use reader

The reaction tubes in the Test Base contain the reagents required for amplification of the target nucleic acid and an internal control. Alere™ i Influenza A & B utilizes a pair of templates (similar to primers) for the specific amplification of RNA from influenza A and B and a fluorescently labeled molecular beacon designed to specifically identify the amplified RNA targets.

Alere™ i Influenza A & B is performed within the confinement of the Test Base, and no other part of the Alere™ i Instrument has contact with the sample during the amplification process. This reduces the risk of instrument contamination and sample carry-over between measurements.

To perform the assay, the Sample Receiver and Test Base are inserted into the Alere™ i Instrument and the elution buffer is automatically heated by the instrument. The sample is added to the Sample Receiver and transferred via the Transfer Cartridge to the Test Base, resuspending the lyophilized pellets contained within the Test Base and initiating target amplification. Heating, mixing and detection by fluorescence is provided by the instrument, with results automatically reported.

Results are displayed by the Alere™ i Instrument and are also stored in an on-board archive and are assigned to a sample ID that has been entered into the Alere™ i Instrument by the operator, and the date/time the test was performed. Data can be retrieved and downloaded by the operator at any time after testing. An external Alere™ Universal Printer can be attached via USB to the Alere™ i Instrument to print test results.

INTENDED USE

The Alere™ i Influenza A & B assay performed on the Alere™ i Instrument is a rapid molecular *in vitro* diagnostic test utilizing an isothermal nucleic acid amplification technology for the qualitative detection and discrimination of influenza A and B viral RNA in direct nasal swabs and nasal or nasopharyngeal swabs eluted in viral transport media from patients with signs and symptoms of respiratory infection. It is intended for use as an aid in the differential diagnosis of influenza A and B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay is not intended to detect the presence of influenza C virus.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Performance characteristics for influenza A were established during the 2012-2013 and the 2014-2015 influenza seasons when influenza A/H3 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.

TECHNOLOGICAL CHARACTERISTICS

Alere™ i Influenza A & B is an instrument-based, molecular *in vitro* diagnostic test utilizing isothermal nucleic acid amplification technology for the qualitative detection of influenza A and B viral RNA.

DEVICE COMPARISON

Alere Scarborough, Inc. is submitting this Special 510(k) submission due to a modification of Alere™ i Influenza A & B in which an additional molecular beacon was added to address an identified mismatch with certain Flu B strains and the sugar excipient was modified to enable more efficient lyophilization.

Alere™ i Influenza A & B incorporating the assay modifications (modified device) was compared to the legally marketed predicate device, the 510(k) cleared Alere™ i Influenza A & B test.

Parameter	Alere™ i Influenza A & B (Modified Device)	Alere™ i Influenza A & B (K151464)
FDA Product Code	OCC,OZE, OOI	Same
Assay Target	Influenza A, Influenza B	Same
Intended Use	The Alere™ i Influenza A & B assay performed on the Alere™ i Instrument is a rapid molecular <i>in vitro</i> diagnostic test utilizing an isothermal nucleic acid amplification technology for the qualitative detection and discrimination of influenza A and B viral RNA in direct nasal swabs and nasal or nasopharyngeal swabs eluted in viral transport media from patients with signs and symptoms of respiratory infection. It is intended for use as an aid in the differential diagnosis of influenza A and B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay is not intended to detect the presence of influenza C virus. Negative results do not preclude influenza virus infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Performance characteristics for influenza A were established during the 2012-2013 and the 2014-2015 influenza seasons when influenza A/H3 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	Same

Parameter	Alere™ i Influenza A & B (Modified Device)	Alere™ i Influenza A & B (K151464)
	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.	
Intended Environment for Use	Professional use, in a medical laboratory or point of care	Same
Instrumentation	Alere™ i Instrument	Same
Self-Contained System	Integrated PC, Software, and Touch Screen Display	Same
Automated Assay	Yes. Sample preparation, amplification, detection, and result interpretation.	Same
Assay Information		
Sample Type	Nasal Swab and Nasal or Nasopharyngeal Swabs Eluted in Viral Transport Media	Same
Influenza A Viral Target	PB2 segment	Same
Influenza B Viral Target	PA segment	Same
Technology	Isothermal nucleic acid amplification for detecting the presence/absence of viral RNA in clinical specimens	Same
Detection Method	Assay uses different reporter dyes for each target	Same
Internal Control	Yes	Same
Result Interpretation	Automated	Same
Assay Result	Qualitative	Same
Time to Result	< 15 minutes	Same