DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 16, 2015

ALERE SCARBOROUGH, INC.
ANGELA DRYSDALE
VP REGULATORY & CLINICAL AFFAIRS-INFECTIOUS DISEASE
10 SOUTHGATE ROAD
SCARBOROUGH ME 04074

Re: K151690
Trade/Device Name: Alere™ i Instrument,
Alere™ i Influenza A & B,
Alere™ i Strep A
Regulation Number: 21 CFR 862.2570
Regulation Name: Instrumentation for clinical multiplex test systems
Regulatory Class: II
Product Code: OOI, OCC, OZE, PGX
Dated: June 22, 2015
Received: June 23, 2015

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,

Ribhi Shawar -S
2015.07.16 13:25:50 -04'00' For

Sally A. Hojvat, M.Sc., 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)*
k151690

Device Name
Alere™ i Instrument,
Alere™ i Influenza A & B,
Alere™ i Strep A

Indications for Use *(Describe)*

Alere™ i Influenza A & B:

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 nasal swabs 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 influenza season 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.

Alere™ i Strep A:

Alere™ i Strep A is a rapid, instrument-based, molecular in vitro diagnostic test utilizing isothermal nucleic acid amplification technology for the qualitative detection of Streptococcus pyogenes, Group A Streptococcus bacterial nucleic acid in throat swab specimens obtained from patients with signs and symptoms of pharyngitis. It is intended to aid in the rapid diagnosis of Group A Streptococcus bacterial infections.

All negative test results should be confirmed by bacterial culture because negative results do not preclude infection with Group A Streptococcus and should not be used as the sole basis for treatment.

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: K151690

SUBMITTER
Alere Scarborough, Inc.
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Establishment Registration Number: 1221359

CONTACT PERSON
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DATE PREPARED
7/14/2015

TRADE NAME
Alere™ i Instrument
Alere™ i Influenza A & B
Alere ™ i Strep A

COMMON NAME
Alere™ i flu, Alere™ i, Alere™ Influenza A & B
Alere™ i Strep, Alere™ i, Alere™ Strep A

REGULATION NAME
Instrumentation for Clinical Multiplex Test Systems (per 21 CFR 862.2570)
Respiratory Viral Panel Multiplex Nucleic Acid Assay (per 21 CFR 866.3980)
Groups A, C and G Beta Hemolytic *Streptococcus* Nucleic acid Amplification System (per 21 CFR 866.2680)

CLASSIFICATION
Class II

PRODUCT CODES
OOI,
OCC, OZE,
PGX

PANEL
Microbiology (83)

PREDICATE DEVICES
Alere™ i Influenza A & B, K141520
Alere ™ i Strep A, K141757

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 collected from patients presenting with signs and symptoms of respiratory infection. Alere™ i Strep A is a rapid, instrument-based isothermal test for the qualitative detection of Group A Strep from throat swab specimens. Both Alere™ i Influenza A & B and Alere™ i Strep A Systems utilize isothermal nucleic acid amplification technology and are 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 Alere™ i Influenza A & B 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.

The reaction tubes in the Alere™ i Strep A Test Base contain the reagents required for Group A Strep bacterial lysis and the subsequent amplification of the target nucleic acid and an internal control. Alere™ i Strep A utilizes a pair of templates (similar to primers) for the specific amplification of DNA from Group A Strep and a fluorescently labeled molecular beacon designed to specifically identify the amplified nucleic acid target.

Both assays are 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 bacterial lysis (for Alere™ i Strep A) and 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 nasal swabs 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 influenza season 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.

Alere™ i Strep A is a rapid, instrument-based, molecular *in vitro* diagnostic test utilizing isothermal nucleic acid amplification technology for the qualitative detection of *Streptococcus pyogenes*, Group A *Streptococcus* bacterial nucleic acid in throat swab specimens obtained from patients with signs and symptoms of pharyngitis. It is intended to aid in the rapid diagnosis of Group A *Streptococcus* bacterial infections.

All negative test results should be confirmed by bacterial culture because negative results do not preclude infection with Group A *Streptococcus* and should not be used as the sole basis for treatment.

TECHNOLOGICAL CHARACTERISTICS

Both assays are rapid, instrument-based, molecular *in vitro* diagnostic tests utilizing isothermal nucleic acid amplification technology for the qualitative detection of influenza A and B viral RNA or *Streptococcus pyogenes*, Group A *Streptococcus* bacterial nucleic acid.

DEVICE COMPARISON

The purpose of this submission is due to a modification of the software contained on the Alere™ i Instrument, there have been no changes to the Alere™ i Influenza A & B or Alere™ i Strep A tests. To enable launch of the Alere™ i Strep A test on the Alere™ i platform, a modification to the software was required to allow the user to run both the Alere™ i Influenza A & B and Alere™ i Strep A assays on the same instrument.

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

Parameter	Alere™ i Influenza A & B (with software modification)	Alere™ i Influenza A & B (K141520)
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 *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 nasal swabs 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	Same

Parameter	Alere™ i Influenza A & B (with software modification)	Alere™ i Influenza A & B (K141520)
	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 influenza season 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.	
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	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

Parameter	Alere™ i Influenza A & B (with software modification)	Alere™ i Influenza A & B (K141520)
Instrument software	Allow the user to run both the Alere™ i Influenza A & B and Alere™ i Strep A assays on the same instrument.	Allow the user to run only the Alere™ i Influenza A & B assay

Alere™ i Strep A incorporating the software modification was compared to the legally marketed predicate device, the 510(k) cleared Alere™ i Strep A test.

Parameter	**Alere™ i Strep A (with software modification)**	**Alere™ i Strep A (K141757)**
FDA Product Code	PGX, OOI	Same
Assay Target	*Streptococcus pyogenes*	Same
Intended Use	**Alere™ i** Strep A is a rapid, instrument-based, molecular *in vitro* diagnostic test utilizing isothermal nucleic acid amplification technology for the qualitative detection of *Streptococcus pyogenes*, Group A *Streptococcus* bacterial nucleic acid in throat swab specimens obtained from patients with signs and symptoms of pharyngitis. It is intended to aid in the rapid diagnosis of Group A *Streptococcus* bacterial infections. All negative test results should be confirmed by bacterial culture because negative results do not preclude infection with Group A *Streptococcus* and should not be used as the sole basis for treatment,	Same
Instrumentation	**Alere™ i** Instrument	Same
Assay Information		
Sample Type	Throat Swab	Same
Target Analyte	Group A *Streptococcus* (*Streptococcus pyogenes*)	Same
Technology	Isothermal nucleic acid amplification	Same
Internal Control	Yes	Same
Result Interpretation	Automated	Same
Assay Result	Qualitative	Same
Time to Result	< 8 minutes	Same
Instrument software	Allow the user to run both the Alere™ i Influenza A & B and Alere™ i Strep A assays on the same instrument.	Allow the user to run only the Alere™ i Strep A assay

SOFTWARE VALIDATION

Software verification and validation studies performed demonstrated that Alere™ i Influenza A & B and Alere™ i Strep A assay functionality remains unchanged due to this change.

The results of the software validation studies performed with the Alere™ i Instrument, demonstrate the Alere™ i Influenza A & B and Alere™ i Strep A tests performed on the Alere™ i Instrument containing modified software is substantially equivalent to the current legally marketed device, Alere™ i Influenza A & B and Alere™ i Strep A performed on the Alere™ i Instrument.