July 11, 2019

Abbott Diagnostics Scarborough, Inc.
Angela Drysdale
VP, Regulatory Affairs - Infectious Disease
10 Southgate Road
Scarborough, Maine 04074

Re: K191534
Trade/Device Name: ID NOW Influenza A & B 2
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory Viral Panel Multiplex Nucleic Acid Assay
Regulatory Class: Class II
Product Code: OCC, OZE, OOI
Dated: June 7, 2019
Received: June 12, 2019

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Uwe Scherf, M. Sc., Ph.D.
Director Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

**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: K191534

**SUBMITTER**

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Road
Scarborough, ME 04074
Establishment Registration Number: 1221359

**PRIMARY CONTACT PERSON**

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Angela.drysdale@alere.com (email)

**DATE PREPARED**

6/7/2019

**TRADE NAME**

ID NOW Influenza A & B 2, Alere™ i Influenza A & B 2

**COMMON NAME**

ID NOW Flu 2, Alere™ i Flu 2, Alere™ Influenza A & B 2

**CLASSIFICATION NAME**

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

**CLASSIFICATION**

Class II

**PRODUCT CODE**

OCC, OZE, OOI

**PANEL**

Microbiology (83)

**PREDICATE DEVICE**

ID NOW Influenza A & B 2, K190204

**DEVICE DESCRIPTION**

ID NOW Influenza A & B 2 is a rapid, instrument-based isothermal test for the qualitative detection and differentiation of influenza A and influenza B from nasal swab or nasopharyngeal swabs tested directly or after elution in viral transport media collected from patients presenting with signs and symptoms of respiratory infection.

The ID NOW Influenza A & B 2 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
- ID NOW 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. ID NOW Influenza A & B 2 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.

ID NOW Influenza A & B 2 is performed within the confinement of the Test Base, and no other part of the ID NOW 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 ID NOW 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 ID NOW Instrument and are also stored in an on-board archive and are assigned to a sample ID that has been entered the ID NOW 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 ID NOW Instrument to print test results.

**INTENDED USE**

The ID NOW Influenza A & B 2 assay performed on the ID NOW 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 or nasopharyngeal 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.

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 ID NOW Instrument. A modification of ID NOW Influenza A & B 2 algorithm was made to optimize recognition of partial/non-dispense of sample into the Test Base that result in a high baseline and to prevent false invalids due to system noise in the Normalization Window.

This is an algorithm update only, there have been no changes made to the chemistry of the assay.

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

| Parameter | ID NOW Influenza A & B 2 (with labeling modification) | ID NOW Influenza A & B 2 (K190204) |
|---|---|---|
| FDA Product Code | OCC, OZE, OOI | Same |
| Assay Target | Influenza A, Influenza B | Same |
| Intended Use | The ID NOW Influenza A & B 2 assay performed on the ID NOW 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 or nasopharyngeal 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.<br><br>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.<br><br>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. | Same |
| Intended Environment for Use | Professional use, in a medical laboratory or point of care | Same |
| Instrumentation | ID NOW Instrument | Same |
| **Assay Information** | | |
| Sample Type | Nasal or Nasopharyngeal 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 | Same |
| Internal Control | Yes | Same |
| Result Interpretation | Automated | Same |
| Assay Result | Qualitative | Same |
| Time to Result | 13 minutes or less | Same |