Abbott Diagnostics Scarborough, Inc.
Jessica Stahle
Manager Regulatory Affairs
10 Southgate Road
Scarborough, Maine 04074

Date: June 24, 2022

Re: K220801
Trade/Device Name: ID Now Instrument, ID Now Influenza A & B 2, ID NOW Strep A 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, PGX
Dated: March 16, 2022
Received: March 18, 2022

Dear Jessica Stahle:

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,

Himani Bisht, Ph.D.
Assistant Director
Viral Respiratory and HPV Branch
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220801

Device Name
ID NOW Influenza A & B 2

Indications for Use *(Describe)*
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.

Performance characteristics for influenza A were established during the 2016-2017 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220801

Device Name
ID NOW Strep A 2

Indications for Use *(Describe)*
ID NOW™ Strep A 2 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.

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 SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K220801

SUBMITTER
Abbott Diagnostics Scarborough , Inc.
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Scarborough, Maine 04074
Establishment Registration Number: 1221359

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DATE PREPARED
3/16/2022

TRADE NAME
ID NOW™ Influenza A & B 2
ID NOW™ Strep A 2

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

CLASSIFICATION NAME
Respiratory Viral Panel Multiplex Nucleic Acid System (per 21 CFR 866.3980)
Streptococcus spp Nucleic Acid-Based Assay (per 21 CFR 866.2680)
Instrumentation for Clinical Multiplex Test Systems (per 21 CFR 862.2570)

CLASSIFICATION
Class II

PRODUCT CODE
OCC, OZE, OOI
PGX, OOI

PANEL
Microbiology (83)

PREDICATE DEVICE
ID NOW™ Influenza A & B 2, K171792
ID NOW™ Strep A 2, K173653

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.

ID NOW™ Strep A 2 is a rapid, instrument-based isothermal test for the qualitative detection of Group A Strep from throat swab specimens.

All ID NOW™ assays 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
- ID NOW™ Instrument – repeat use reader

The reaction tubes in the ID NOW™ Influenza A & B 2 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.

The reaction tubes in the ID NOW™ Strep A 2 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. ID NOW™ Strep A 2 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.

All ID NOW™ assays are 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 bacterial lysis (for ID NOW™ Strep A 2) and 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 into 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 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.

Performance characteristics for influenza A were established during the 2016-2017 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.

ID NOW™ Strep A 2 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.

COMPARISON TO THE PREDICATE

The purpose of this Special 510(k) submission is to bring to market a modification of the software contained on the ID NOW™ Instrument. A modification of the ID NOW™ Influenza A & B 2 and ID NOW™ Strep A 2 algorithm was made to mitigate issues with false invalid results due to baseline values that are lower than allowed by the algorithm and incorrectly identified as Empty Tube Values. This is an algorithm update only, there have been no changes made to the chemistry of the assays.

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.

Parameter	ID NOW™ Influenza A & B 2 (with software modification)	ID NOW™ Influenza A & B 2 (K171792)
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. 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 2016-2017 influenza season when influenza A/H3 and A/H1N1	Same

Parameter	ID NOW™ Influenza A & B 2 (with software modification)	ID NOW™ Influenza A & B 2 (K171792)
	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	ID NOW™ Instrument	Same
Assay Information		
Sample Type	Nasopharyngeal Swab, 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	Same
Internal Control	Yes	Same
Result Interpretation	Automated	Same
Assay Result	Qualitative	Same
Time to Result	< 15 minutes	Same

ID NOW™ Strep A 2 incorporating the software modification was compared to the legally marketed predicate device, the 510(k) cleared ID NOW™ Strep A 2.

Parameter	ID NOW™ Strep A 2 (with software modification)	ID NOW™ Strep A 2 (K173653)
FDA Product Code	PGX, OOI	Same
Assay Target	*Streptococcus pyogenes*	Same
Intended Use	ID NOW™ Strep A 2 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.	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	Throat Swab	Same
Target Analyte	Group A *Streptococcus* (*Streptococcus pyogenes*)	Same

Parameter	ID NOW™ Strep A 2 (with software modification)	ID NOW™ Strep A 2 (K173653)
Technology	Isothermal nucleic acid amplification	Same
Internal Control	Yes	Same
Result Interpretation	Automated	Same
Assay Result	Qualitative	Same
Time to Result	< 8 minutes	Same