DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 24, 2016

Becton, Dickinson & Co.
Gregory Payne,
Director of Regulatory Affairs
10865 Road to the Cure, Suite 200
San Diego, CA 92121

Re: K160161
Trade/Device Name: BD Veritor System for Rapid Detection of Flu A + B CLIA waived Kit
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza virus serological reagents
Regulatory Class: I
Product Code: GNX
Dated: January 22, 2016
Received: January 27, 2016

Dear Mr. Payne:

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,

Tamara V. Feldblyum -S for

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

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)*
K160161

Device Name

BD Veritor(TM) System for Rapid Detection of Flu A + B CLIA waived Kit

Indications for Use *(Describe)*

The BD Veritor System for Rapid Detection of Flu A+B is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasal and nasopharyngeal swabs of symptomatic patients. The BD Veritor System for Rapid Detection of Flu A+B (also referred to as the BD Veritor System and BD Veritor System Flu A+B) is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. A negative test is presumptive and it is recommended that these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Outside the U.S., a negative test is presumptive and it is recommended that these results be confirmed by viral culture or a molecular assay cleared for diagnostic use in the country of use. FDA has not cleared this device for use outside of the U.S. 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. The test is not intended to detect influenza C antigens.

Performance characteristics for influenza A and B were established during January through March of 2011 when influenza viruses A/2009 H1N1, A/H3N2, B/Victoria lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled "Update: Influenza Activity—United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses.

If infection with a novel influenza 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 the state or local health department for testing. Virus 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

DATE PREPARED: January 22, 2016

SUBMITTED BY: BD Diagnostic Systems, Point of Care
10865 Road to the Cure, Suite 200
San Diego, CA 92121
Tel: (858) 795-7890
Fax: (858) 812-8505

CONTACT NAME: Gregory P. Payne, RAC, Director Regulatory Affairs

DEVICE TRADE NAME: BD Veritor™ System for Rapid Detection of Flu A + B CLIA waived Kit

DEVICE COMMON NAME: Influenza virus serological reagents

DEVICE CLASSIFICATION: 21 CFR 866.3330

CLASSIFICATION: CLASS I

PANEL: Microbiology

PREDICATE DEVICES : BD Veritor™ System for Rapid Detection of Flu A+B CLIA waived kit (k112277 ,k132259, k132692, k151291, k152870)

INTENDED USE :

CLIA waived kit

The BD Veritor System for Rapid Detection of Flu A+B CLIA waived assay is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasal and nasopharyngeal swabs of symptomatic patients. The BD Veritor System for Rapid Detection of Flu A+B (also referred to as the BD Veritor System and BD Veritor System Flu A+B) is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. A negative test is presumptive and it is recommended that these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Outside the U.S., a negative test is presumptive and it is recommended that these results be confirmed by viral culture or a molecular assay cleared for diagnostic use in the country of use. FDA has not cleared this device for use outside of the U.S. 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. The test is not intended to detect influenza C antigens. Performance characteristics for influenza A and B were established during January through March of 2011 when influenza viruses A/2009 H1N1, A/H3N2, B/Victoria lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled “Update: Influenza Activity—United States, 2010-2011 Season, and Composition of the 2011-

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2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses. If infection with a novel influenza 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 the state or local health department for testing. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

DEVICE DESCRIPTION :

The BD Veritor™ Flu A+B test is an immunochromatographic assay for the qualitative detection of influenza A and B viral antigens in respiratory specimens. The patient specimen is mixed in a reaction tube prefilled with RV Reagent C, gently mixed, and then added to the test device. RV Reagent C contains mucolytic agents that function to break down mucus in a patient specimen thereby exposing viral antigens and enhancing detection in the assay device. Processed specimens are expressed through a filter tip into a single sample well on the BD Veritor™ Flu A+B test device.

After addition to the test device, any influenza A or influenza B viral antigens present in the specimen bind to anti-influenza antibodies conjugated to detector particles on the Veritor™ Flu A+B test strip. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of antibody striped on the membrane. The Veritor™ Flu A+B test devices are designed with five spatially-distinct zones including positive and negative control line positions, separate test line positions for the target analytes, and a background zone. The test lines for the target analytes are labeled on the test device as 'A' for Flu A position, and 'B' for Flu B position. The onboard positive control ensures the sample has flowed correctly and is indicated on the test device as 'C'. Two of the five distinct zones on the test device are not labeled. These two zones are an onboard negative control line and an assay background zone. The onboard negative control zone addresses non-specific signal generation. The remaining zone is used to measure the assay background.

The BD Veritor™ Flu A+B assay incorporates an active negative control feature in each test to identify and compensate for sample-related, nonspecific signal generation. The BD Veritor™ System Reader uses a proprietary algorithm that subtracts nonspecific signal at the negative control line from the signal present at both the Flu A and Flu B test lines. If the resultant test line signal is above a pre-selected assay cutoff, the specimen scores as positive. If the resultant test line signal is below the cutoff, the specimen scores as negative. Use of the active negative control feature allows the BD Veritor™ System reader to correctly interpret test results that cannot be scored

Positive Ctrl	**C**
Flu B test line	**L4**
Flu A test line	**L3**
Negative Ctrl	**L2**
Background	

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visually because the human eye is unable to accurately perform the subtraction of the nonspecific signal.

DEVICE COMPARISON:

The labeling has been changed to reflect the addition of strain reactivity data for the following strains:

Strain	subtype
A/Northern Pintail/Washington/40964/2014	H5N2
A/Gyrfalcon/Washington/41088-6/2014	H5N8

SUBSTANTIAL EQUIVALENCE:

The modified BD Veritor™ System Flu A+ B CLIA waived kit device is substantially equivalent to the current legally marketed, BD Veritor™ System Flu A+B CLIA waived kit device assay. Additions made to the labeling to add additional strain testing did not change the intended use of the device or the fundamental scientific technology.

A Risk Analysis was conducted and is detailed in the Design Control Summary Section. No new issues of safety and effectiveness were identified during this process.

Additions are as follows:

Change		Potential Impact of Change
Addition of data for Strain reactivity of:		Additional information provided to users regarding strain reactivity.
A/Northern Pintail/Washington/40964/2014	H5N2	
A/Gyrfalcon/Washington/41088-6/2014	H5N8	