SPECIAL 510(k): Device Modification
OIR Decision Summary

To: Becton Dickinson and Company **RE:** K151291

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device(s).

   Trade Name: BD Veritor™ System Flu A+B (Physician Office Kit)
   510(k) numbers: K112277, K132259, K132692

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use and package labeling.

   Submitter provided a checklist indicating "yes" to the statement "Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).

3. A description of the device **MODIFICATIONS** demonstrating that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed.**

   Submitter provided the following statement indicating that the device's scientific technology is unchanged.
   The BD Veritor™ System Flu A + B (Physician Office Kit) is substantially equivalent to the current legally marketed device, BD Veritor™ System Flu A + B (Physician Office Kit). Modifications made to the BD Veritor™ System Flu A + B (Physician Office Kit) product did not change the intended use of the device or the fundamental scientific technology.

   The modification presented in this 510(k) consisted of an expanded analytical reactivity table to include additional reactivity information for nine strains of the influenza A virus and five strains of the influenza B virus, including the minimal concentration detected for these 14 influenza viruses. The following tables show the viruses tested for this submission and the minimal detected concentration:

Strain	Subtype	Minimal Detected Concentration
A/Fujian-Gulou/1896/2009	H1N1	4.50×10^5 $CEID_{50}$/mL
A/Washington/24/2012	H1N1	3.16×10^4 EID_{50}/mL
A/Switzerland//9715293/2013	H3N2	3.25×10^2 $TCID_{50}$/mL
A/Texas/50/2012	H3N2	1.75×10^3 $TCID_{50}$/mL
A/Anhui/01/2005	H5N1	0.512 HA
A/Vietnam/1203/2004	H5N1	0.512 HA
A/Pheasant/New Jersey/1355/1998	H5N2	0.256 HA
A/Mallard/Netherlands/12/2000	H7N7	0.256 HA
A/Chicken/Hong Kong/G9/1997	H9N2	1.024 HA

$TCID_{50}$= 50% Tissue Culture Infectious Dose
$CEID_{50}$= 50% Chicken Embryo Infectious Dose
EID_{50}= 50% Egg Infectious Dose
HA= Hemagglutination Assay Titer

Strain	Minimal Detected Concentration
B/Massachusetts/2/2012 (Yamagata Lineage)	1.25×10^6 $CEID_{50}$/mL
B/Montana/5/2012 (Victoria-like)	3.14×10^5 EID_{50}/mL
B/Phuket/3073/2013	6.08×10^3 $TCID_{50}$/mL
B/Texas/06/2011 (Yamagata Lineage)	6.20×10^5 $CEID_{50}$/mL
B/Wisconsin/01/2010 (Yamagata Lineage)	7.00×10^2 $CEID_{50}$/mL

$TCID_{50}$= 50% Tissue Culture Infectious Dose
$CEID_{50}$= 50% Chicken Embryo Infectious Dose
EID_{50}= 50% Egg Infectious Dose

The BD Veritor™ System Flu A+B (Physician Office Kit) labeling has been updated to include this additional analytical reactivity information.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, and physical characteristics:

Similarities:

Similarities Item	Predicate Device	Proposed Device
Features	**BD Veritor™ System Flu A+B assay**	**BD Veritor™ System Flu A+B assay**
Intended Use	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 nasopharyngeal and nasal swabs of symptomatic patients. The BD Veritor System for Rapid Detection of 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.	Same
Read Results	BD Veritor System Reader	Same

Specimen Types	Nasal swab, nasopharyngeal swab	Same
Read Result Time	10 minutes	Same
External Controls	Test kit contains Positive and Negative Control swabs	Same

Differences:
The modified device differs from the currently marketed BD Veritor™ System Flu A+B (Physician Office Kit) in the following way:

The labeling has been updated to reflect the addition of influenza A and B strain analytical reactivity data and the lowest concentration detected for each of the tested strains. Footnotes explaining TCID50/mL, EID50/mL, CEID50/mL, and HA have been added to the "Analytical Sensitivity (Limit of Detection)" table and the "Strain Reactivity with Influenza A and B Viruses" table in the package insert.

5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   BD's Risk Assessment process is based on a BD Product Risk Management procedure which meets the requirement for risk management as set forth in ISO 14971:2007 and EN ISO 14971:2012. Using this procedure, the following are estimated:

   - the Hazard,
   - the Adverse Effect(Harm to Patient),
   - the Potential Causes of the Hazard,
   - The probability of severity and the probability of occurrence are estimated.

   Based on a resulting calculated Risk Index*, Risk Control Measures are identified, required verification and validation activities are determined, and verification of the effectiveness of risk control measures is determined.

   *Risk Index:

   Insignificant (GR) – individual risks in the green region are deemed negligible in comparison with other risks and in relation to the benefit of using the product. Even if the risk falls into this region, the risk must be reduced as far as possible. For risks falling into this region, the medical benefit is considered to outweigh the individual residual risk since the combination of the occurrence and severity is considered low. These risks do not require individual risk benefit analysis. Because risk of harm in this region are deemed negligible, risk control measures implemented in this region, will not require documented verification of risk control measure effectiveness.

   Investigate (YE) –individual risks in the yellow region are not negligible in comparison with other risks, therefore further risk reduction must be investigated. This category requires evaluation for risk reduction and once all possible risk control measures have been implemented, the residual risk is not reduced to insignificant (GR) is not possible, the individual item in this region require a documented risk/benefit analysis to document acceptance of the residual risk (See Attachment 3 for a Risk Benefit Analysis model.

   Unacceptable/Intolerable (RE) – individual risks in the red region are unacceptable. This region requires the implementation of risk control measures to reduce the risk. In general, BDDS products should not have items with residual risks falling into this region. However, in an exceptional and rare circumstance, these items may be documented in the risk/benefit analysis with approval by Medical Affairs at a director level or higher.

RESULTS OF THE ANALYSIS:

The results of the analysis indicated an initial possible combination of severity and occurrence that fell into S-3/P-3 category (i.e., Risk Index of "Investigate"):

Hazard	Adverse Effect (Harm)	Probability of Severity	Potential Causes of the Hazard	Probability of Occurrence	Existing Risk Control Measure	Risk Index *	Responsibility for Risk Control Measure	Risk Control Measure
False Negative	Effect on patient is that they could be inappropriately treated leading to flu progression	S-3	Assay does not detect the predicted strains for 2015/2016 Flu Season or other available new and circulating strains	P-3	Current strain reactivity has been determined and is provided in the Product Insert	YE	R&D	**Testing** Obtain and test additional flu strains **Labeling** Update PI with new reactivity after FDA special 510(k) clearance

b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used, and acceptance criteria to be applied

To implement the indicated investigation, Protocol SDSP15001 was developed and approved based on previously accepted FDA submissions regarding strain reactivity. Specific influenza strains selection for this reactivity study was based on new circulating strains for 2015/2016 Influenza Season, as well as availability of other strains through CDC and WHO. Acceptability criteria were the ability of the BD Veritor™ System Flu A+B (Physician Office Kit) to detect these additional influenza strains.

Analytical Reactivity Testing was conducted as described in section 3, Device Modifications.

BD Veritor™ System Flu A+B (Physician Office Kit) was successful in detecting all strains tested. The acceptance criteria were fully met. The package insert was updated to include the data obtained during this strain reactivity testing. The results of the strain reactivity testing reduced the probability of occurrence from P-3 to P-1 and reduced the Risk Index to the "Insignificant" category:

Risk Control Measure	Risk Control Measure Effectiveness Reference	Probability of Severity	Probability of Occurrence	Risk Index
Testing Obtain and test additional flu strains **Labeling** Update PI with new reactivity after FDA special 510(k) clearance	SDSP15001	S-3	P-1	GR

c) Declaration of Conformity with Design Controls

A "Declaration of Conformity with Design Controls" statement was submitted for the validation activities and manufacturing facility by the Director of Regulatory Affairs and Quality Systems. The statement indicates that;

1) To the best of knowledge of the Director of Regulatory Affairs and Quality Systems, the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.
2) The manufacturing facility, BD Rapid Diagnostics Co Ltd, is in conformance with the design control requirements as specified in 21 CFR 820. 30 and the records are available for review.

6. A **Truthful and Accurate Statement**, a **510(k) Summary**, and the **Indications for Use Enclosure**.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modifications and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared device.