SPECIAL 510(k): Device Modification
OIR Decision Summary

To: Becton, Dickinson and Company **RE:** K152874

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own 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:

   Device Trade Name:
   BD Veritor™ System for Rapid Detection of Flu A+B Laboratory Kit

   510(k) numbers:
   k120049, k121797, k132256, k132693, k133138, k151301

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.

3. The submitter stated that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device has not changed, and provided a description of the device **MODIFICATIONS made in this 510(k). The purpose of this special 510(k) is to provide** additional information to add to the analytical reactivity table in the package insert showing the ability of the device to detect recently circulating influenza strains at the concentrations shown below.

   The modification presented in this special 510(k) is the inclusion of one influenza A strain and five influenza B strains to the Strain Reactivity with Influenza A and B Viruses section of the BD Veritor™ System for Rapid Detection of Flu A+B Laboratory Kit Assay package insert. A list of the strains tested is included below.

Strain	Final Dilution Factor	Estimated LOD [1]
A/California/02/2014 (H3N2)	4000	$1.45 \times 10^2 TCID_{50}/mL$
B/Brisbane/33/2008 (Victoria Lineage)	200	2.45×10^5 $CEID_{50}/mL$
B/Guangdong-Liwan/1133/2014 (Yamagata Lineage)	2000	9.0×10^5 $CEID_{50}/mL$
B/Hong Kong/259/2010 (Victoria Lineage)	400	1.35×10^6 $CEID_{50}/mL$
B/Texas/02/2013 (Victoria Lineage)	4000	2.75×10^4 $CEID_{50}/mL$
B/Utah/09/2014 (Yamagata Lineage)	10000	6.3×10^3 $CEID_{50}/mL$

[1]Estimated LOD is the lowest concentration of influenza A and B virus strains that can be detected by the BD VeritorTM System Flu A + B Assay in 3/3 replicates.

The BD Veritor™ System for Rapid Detection of Flu A+B Laboratory Kit Assay package insert 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, physical characteristics:

Product Feature	**Currently Marketed Veritor™ System Flu A + B Laboratory Kit (k 151301)**	**Product Modification**
Similarities:		
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 wash, aspirate and swab in transport media samples from 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 outside 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 nasopharyngeal (NP) washes/aspirates 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. Performance characteristics for influenza A and B NP swabs in transport media were established	unchanged

Product Feature	Currently Marketed Veritor(TM) System Flu A + B Laboratory Kit (K151301)	Product Modification
	during January through April of 2012 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, 2011-2012 Season, and Composition of the 2012-2013 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.	
Specimen type	Nasopharyngeal swabs in transport media and nasopharyngeal wash aspirates	unchanged
Assay technology	Immunochromatographic	unchanged
Detection Format	An opto-electronic reader determines the line intensity at each of the spatially defined test and control line positions, interprets the results using a scoring algorithm and reports a positive, negative or invalid result on the LCD screen based on pre-set thresholds.	unchanged
Qualitative or Quantitative	Qualitative	unchanged
Assay run time	approximately 10 minutes	unchanged
Control format	• Kit Flu A+/B- dry swab procedural control • Kit Flu A-/B+ dry swab procedural control • Internal positive control • Internal negative control	unchanged
Detection of Flu A and B viruses	differentiation A vs. B	unchanged
Differences:		

Product Feature	Currently Marketed Veritor™ System Flu A + B Laboratory Kit (k 151301)	Product Modification
Analytical Strain Reactivity Tables in Labeling (Package Insert)	Current Product Package Insert includes 73 Flu Strains; 36 Flu A and 37 Flu B in the Analytical Strain reactivity tables.	Analytical Strain reactivity tables on pages 60-61 of the proposed Package Insert will contain data regarding 6 additional Influenza strains

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

      The Risk Assessment process used was based on a BD Product Risk Management procedure which, according to the sponsor, meets the requirement for risk management as set forth in ISO 14971:2007 and EN ISO 14971:2012.

      Using this procedure, the following were estimated and the results are in the table below under 5b:

      - The Hazard,
      - The Adverse Effect (Harm to Patient),
      - The Potential Causes of the Hazard,
      - The probability of Hazard Severity and
      - The probability of Occurrence

   b. Based on the resulting calculated Risk Index, Risk Control Measures were identified, required verification and validation activities were determined, and effectiveness of risk control measures were verified.

      The risk assessment identified the need to confirm the BD Veritor™ System's reactivity to new strains forecast for 2015/2016 Influenza Season.

      The results of the analysis indicated an initial possible combination of severity and occurrence that fell into S-3/P-3 category. To implement the indicated investigation, Protocol SDSP15004 was developed and approved based on previously accepted FDA submissions regarding strain reactivity. The design of the study is replicated from a previous Special 510(k) submission. The acceptability criterion was the ability of the BD Veritor™ test to detect the additional Flu strains. The BD Veritor™ System Flu A+B assay successfully detected all strains tested. The data to be included in the insert are the actual values obtained during this testing. The results of the strain testing reduced the probability of occurrence from P-3 to P-1 and reduced the risk to the "negligible" category.

Hazard	**False Negative**		**Risk Control Measure**	**Testing**
Adverse Effect (Harm)	Effect on patient is that they could be inappropriately treated leading to flu progression			Obtain and test additional flu strains
Probability of Severity	S-3			**Labeling**
Potential Causes of the Hazard	Assay does not detect the predicted strains for 2015/2016Flu Season or other available new and circulating strains			Update PI with new reactivity after FDA special 510(k) clearance
Probability of Occurrence	P-3		**Risk Control Measure Effectiveness Reference**	SDSP15001
Existing Risk Control Measure	Current strain reactivity has been determined and is provided in the Product Insert		**Probability of Severity**	S-3
Risk Index	YE		**Probability of Occurrence**	P-1
Responsibility for Risk Control Measure	R&D		**Risk Index**	GR

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 modification(s) 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