

**SPECIAL 510(k): Device Modification
OIR Decision Summary**

To: THE FILE

RE: DOCUMENT NUMBER K160161

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.

K152870 BD Veritor™ System for Rapid Detection of Flu A+ B CLIA Waived kit

K112277, K132259, K132256, 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.

3. A description of the device **MODIFICATION**, including a statement that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

Changes to the labeling include the addition of two influenza A/H5 strains to the reactivity section of currently marketed BD Veritor™ System Flu A+ B CLIA Waived kit Assay Product Insert. A list of the strains tested is included in Table 1 below.

Table 1

No.	Strain	Final Dilution Factor	Minimal Detected Concentration ¹
1	A/Northern Pintail/Washington/40964/2014 (H5N2)	4000	6.28×10^5 EID ₅₀ /mL
2	A/Gyrfalcon/Washington/41088-6/2014 (H5N8)	8000	1.98×10^6 EID ₅₀ /mL

1. The lowest concentration of influenza A virus strain that can be detected by the BD Veritor™ System Flu A + B Assay in 3/3 replicates.

The fundamental scientific technology of the modified device has not changed.

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

Table 2

Comparison to Predicate Device		
Product Feature	Currently Marketed Veritor™ System Flu A + B CLIA Waived kit (K152870)	Product Modification
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 nasal and	Unchanged

	<p>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.</p> <p>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.</p> <p>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.</p>	
Specimen type	Nasal and nasopharyngeal swabs of symptomatic patients.	Unchanged
Assay technology	Chromatographic immunoassay	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	<ul style="list-style-type: none"> • 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 of Flu A vs. Flu B	Unchanged

Comparison to Predicate Device		
Differences:		
Product Feature	Currently Marketed Veritor™ System Flu A + B CLIA Waived kit (K152870)	Product Modification
Analytical Strain Reactivity Tables in Labeling (Package Insert)	Current Product Package Insert includes 79 Flu Strains; 37 Flu A and 42 Flu B in the Analytical Strain reactivity tables.	Analytical Strain reactivity tables in the Labeling will include two additional Influenza A/H5 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 characteristics were assessed and the results are presented in Table 3 below:

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

Table 3

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	Moderate			Labeling
Potential Causes of the Hazard	Assay does not detect the strains			Update PI with new reactivity after FDA special 510(k) clearance
Probability of Occurrence	Occasional		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	Moderate
Risk Index	Investigate		Probability of Occurrence	Improbable
Responsibility for Risk Control Measure	R&D	Risk Index	Insignificant	

- 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.

The risk assessment identified the need to confirm the Veritor System's reactivity to the CDC H5Nx Virus Panel provided as part of the Pandemic Influenza Preparedness (PIP) Framework and to add the results to a package insert available to the public.

In order to demonstrate reactivity with the A/H5 viruses and present the data in a revised Package Insert, a reactivity study was conducted. The study acceptance criterion was a positive instrument read with samples of the subject influenza viruses when tested by the BD Veritor™ Flu A+B CLIA Waived kit assay.

The lowest concentrations of influenza A/H5 viruses that were detected by the Veritor™ System Flu A+B assay are listed in Table 1. The strain reactivity data provided above and proposed for inclusion into the PI demonstrate that all strains tested met the acceptance criteria.

The studies conducted on the BD Veritor™ System Flu A+B assay support the proposed labeling changes to reflect the analytical reactivity data generated. This data will be used to update the strain reactivity section of the product insert.

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.