SPECIAL 510(k): Device Modification
OIR Review Memorandum (Decision Making Document is Attached)

To: Meridian Bioscience Inc. **RE:** K133714

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:

   TRU FLU

   510(k) number: K092553

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, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

3. Description of the device **MODIFICATION(S):**

The modification presented in this special 510(k) consisted of an expanded LoD table to include information for the H7N9 influenza A virus. The firm tested the ability of the TRU FLU rapid influenza test to detect H7N9 influenza A virus. The virus used (A/Anhui/1/2013) was obtained from the Centers for Disease Control and Prevention by a contracted third party laboratory where it was propagated and retitered. An LoD study was performed with the A/Anhui/1/2013 influenza strain by first estimating the empirical LoD using ten-fold dilutions, followed by two-fold serial dilutions. Each dilution was tested with three replicates. Once the target LoD was identified, confirmatory testing using 20 replicates was performed at that dilution plus one dilution above and below it. The target LoD was confirmed correct when all 20 replicates were determined to be positive for the virus with the assay.

The LoD concentration was determined to be 1.51×10^5 $TCID_{50}$/mL. The TRU FLU package insert has been updated to include the additional LoD information.

4. The **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed.**

5. **Comparison Information**

Similarities

	Predicate Device	Modified Device
	TRU FLU (Unmodified) (K092553)	TRU FLU (K133714)
Intended Use	TRU FLU is a rapid, qualitative, lateral-flow immunochromatographic assay for detecting both influenza A and influenza B viral nucleoprotein antigens in human	TRU FLU is a rapid, qualitative, lateral-flow immunochromatographic assay for detecting both influenza A and influenza B viral nucleoprotein antigens in human

	nasal wash, nasopharyngeal aspirate and nasal and nasopharyngeal swab samples in symptomatic patients. This test is not intended for the detection of influenza C viruses. Negative test results are presumptive and should be confirmed by cell culture. Negative test results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions.	nasal wash, nasopharyngeal aspirate and nasal and nasopharyngeal swab samples in symptomatic patients. This test is not intended for the detection of influenza C viruses. Negative test results are presumptive and should be confirmed by cell culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions.
Reagents /Supplies	Test Device Conjugate Tube Sample Diluent Transfer pipettes	Same
Marketing of system	All reagents and components listed above are marketed as a test kit	Same
Assay Type	Lateral flow immunochromatography	Same
Sample Type	Nasal and nasopharyngeal swab, nasal wash/aspirate	Same
Sample Preparation	6 steps: Nasal wash/aspirate or nasal swab in transport medium 4 steps: Nasal swabs without transport medium	Same
Test Method	11 Steps (see package insert)	Same
Endpoint	Positive = Pink-red band at test and control lines Negative = Pink-red band at control line only	Same

Differences

The package insert has been updated to include detection of the A/Anhui/1/2013 H7N9 virus in the LoD information section:

A/Anhui/1/2013 - A - H7N9 - 1.51×10^5 $TCID_{50}$/mL

Although this test has been shown to detect influenza A (H7N9) virus cultured from positive human respiratory specimens, the performance characteristics of this device with clinical specimens that are positive for H7N9 influenza viruses have not been established. The TRU FLU test can distinguish between influenza A and B viruses, but it cannot differentiate influenza A subtypes.

6. **Design Control Activities Summary**:

Analytical Reactivity Testing was conducted as described in Section 3, page 2 of the submission, "Summary of Design Control Activities".

A "Declaration of Conformity" statement was submitted for the manufacturing facility and validation activities and signed by the Executive Vice President of Research and Development and the Senior Director of Regulatory Affairs and Design Assurance. The statements indicate that:

1. The manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
2. The validation activities, as required by the risk analysis, for the modification were performed by the designated individuals and the results demonstrated that the predetermined acceptance criteria were met.

In conclusion, based on the results of the analytical reactivity testing the modified labeling is truthful and accurate. The changes do not affect the performance of the test and it is therefore substantially equivalent to the current cleared test.

7. Truthful and Accurate Statement, a **510(k) Summary or Statement** 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 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.