SPECIAL 510(k): Device Modification
OIR Decision Summary

To: THE FILE **RE:** DOCUMENT NUMBER K163273

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 (delete/add items as necessary):

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

   Trade Name: TRU LEGIONELLA
   510(k) #: K113190

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device, called TRU LEGIONELLA, 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).

   Submitter states in the submission that the intended use of the modified device has not changed from its predicate.

3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
   The modifcations include the following:

   - Changing the Control Line Antibody from a Goat anti-Rabbit IgG Antibody to a Chicken IgY (IgG) Control Line Antibody paired with a polyclonal Donkey anti-Chicken IgY (IgG) Antibody gold-conjugate,
   - Changing the Test Strip material.

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

Similarities Between the Modified Device and the Predicate Device		
Item	**MODIFIED DEVICE TRU LEGIONELLA® (This Submission)**	**PREDICATE DEVICE TRU LEGIONELLA® (K113190)**
Intended Use	Same as predicate.	The TRU LEGIONELLA® assay is an in vitro, rapid, lateral-flow immunoassay for the qualitative detection of *Legionella pneumophila* serogroup 1 antigen in human urine specimens. It is designed to test specimens from patients with symptoms of pneumonia. Test results are to be used as an aid in diagnosis of *Legionella pneumophila* serogroup 1 infection. A negative result does not preclude infection with *Legionella pneumophila* serogroup 1. Test results are to be used in conjunction with information obtained from the patient's clinical evaluation and other diagnostic procedures.
Specimen Types	Same as the predicate.	Human urine, preserved and unpreserved
Test Strip: Test Line Antibody	Same as the predicate.	Rabbit anti-*L. pneumophila* Serogroup 1
Gold Conjugate: Test Line Antibody	Same as the predicate.	Rabbit anti-*L. pneumophila* Serogroup 1
Reagents/Components	Same as predicate	• Test Strip • Conjugate Tube • Sample Diluent/Negative Control • Positive Control • Plastic transfer pipettes with 100, 200 and 300 µL volume marks
General Laboratory Equipment	Same as the predicate.	• Vortex • Interval timer • Disposable latex gloves
Sample Preparation	Same as the predicate.	1. Add 100 µL of Sample Diluent to Conjugate Tube. Vortex for 10 seconds. 2. Add 100 µL of thoroughly mixed urine sample to the Conjugate Tube. 3. Mix sample and conjugate thoroughly.
Testing Time	Same as the predicate.	Approximately 20 minutes
Visual Read	Same as the predicate.	**Negative:** A PINK-RED band at the Control Line position. No other bands are present. **Positive:** PINK-RED band of any color intensity at the Control and Legionella Test Line positions. **Invalid:** No band at the Control Line position, a pink-red band appearing after 21 minutes of incubation, or a band of any other color than pink-red

Similarities Between the Modified Device and the Predicate Device		
Item	**MODIFIED DEVICE TRU LEGIONELLA® (This Submission)**	**PREDICATE DEVICE TRU LEGIONELLA® (K113190)**
Interfering Substances	Same as predicate	Potentially interfering substances were added to three natural negative and three contrived positive samples. The contrived positive samples were prepared by spiking confirmed negative samples with *Legionella pneumophila* Philadelphia strain antigen at 3.76×10^5 CFU/mL, the limit of detection for this assay. Dilution Controls for each sample were prepared by adding a saline solution in place of the potentially interfering substance. The failure of all three replicates to produce the expected results (positive or negative) is the indicator of interference. Substances tested are as follows: Antihistamine, Ascorbic acid, Bilirubin, Boric acid, Ciprofloxacin, Cold/flu tablets, Cough drops, Cough syrup, Decongestant, Erythomycin, Glucose, Protein (BSA), Rifampicin, Urea, White blood cells, and Whole blood. The tested substances produced no interference with the positive and negative results of TRU LEGIONELLA.

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,

   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 TRU LEGIONELLA device modifications were evaluated by a cross functional team through a product Hazard Analysis and Risk Assessment, including a Failure Mode Effective Analysis. Risk Management activities were carried out in accordance with requirements proscribed in ISO 14971:2007-03-01 (EN ISO14971:2007) and 21 CFR 820. Risks associated with manufacturing activities, final product performance, and potential misuse were considered with severity, detectability and potential frequency of occurrence.

   The potential risks identified for the TRU LEGIONELLA Control Line change were associated with reagent stability and potential impact to performance. Risks were mitigated through in-house analytical studies.

   - Accelerated stability testing was completed as described in ISO 23640, *In vitro diagnostic medical devices– Evaluation of stability of in vitro diagnostic reagents,* to confirm the performance of the modified product through its estimated shelf-life. Three modified kit lots were manufactured and evaluated at two elevated temperatures for the number of days corresponding to the assigned expiration of the

original product configuration. **Accelerated stability testing produced expected results.** The modified TRU LEGIONELLA product is also subject to confirmatory real-time stability studies. Accelerated and real-time stability data is maintained by Meridian according to established document and record control policies.

- Verification studies were completed using fresh and frozen urine specimens classified as positive or negative by the original TRU LEGIONELLA product configuration. All specimens were tested with the modified TRU LEGIONELLA kit according to package insert instructions to confirm agreement with the original product configuration. **All specimens produced expected results in the modified product.**

Based on the findings from the analytical studies, the modifications to TRU LEGIONELLA do not introduce any new risks to the performance of the device and do not alter safety and effectiveness. Results of these studies confirmed that the identified residual risk of the modified control is acceptable with no further mitigation activities required.

c) Declaration of Conformity to Design Controls

A "Declaration of Conformity" statement was submitted by Meridian Biosciences, Inc. The staements are written below. Statement i. was signed by the Director of Immunoassay Development. Statement ii. was signed by the Executive Vice President of Global Regulatory and Quality systems. The statements indicate that:

i. "To the best of my knowledge, the verification activities for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met."
ii. "The manufacturing facility is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review."

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.