

SPECIAL 510(k): Device Modification
OIVD Review Memorandum

To: THE FILE

RE: DOCUMENT NUMBER **K101461**

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

1. The name and 510(k) number of the SUBMITTER'S previously cleared device:
BD Directigen™ EZ Flu A+B test (K042472 and K063689)
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 modification of the device consisted of adding new analytical sensitivity data for two strains of 2009 H1N1 virus, A/California/4/2009 and A/California/7/2009. The reactivity table in the package insert was updated to include the said strains of the virus. **This modification has not had any effect or caused any changes to the FUNDAMENTAL SCIENTIFIC TECHNOLOGY of this device.**
4. **Comparison Information (similarities and differences):**
 - a) There were no changes made to the device.
 - b) Analytical data was generated to determine the reactivity and the minimum level of detection (LOD) of the device with two cultured isolates (A/California/4/09 and A/California/7/09) of the 2009 H1N1 virus.
 - c) The package insert was revised to reflect the new information: the analytical sensitivity table and the strain reactivity table were updated to include the new information.
 - d) The following disclaimer was added under each of the revised tables:
Although this test has been shown to detect the 2009 H1N1 virus cultured from a positive human respiratory specimen, the performance characteristics of this device with clinical specimens that are positive for the 2009 H1N1 influenza virus have not been established. The BD Directigen EZ Flu A+B test can distinguish between influenza A and B viruses, but it cannot differentiate influenza subtypes."
5. **A declaration of conformity with design controls.**

Sponsor provided a signed statement that:

 - a) Verification activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
 - b) 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.
6. **A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).**

Sponsor provided a signed Truthful and Accurate Statement, updated 510(k) summary and Indications for Use Enclosures.

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. I recommend the device be determined substantially equivalent to the previously cleared device.