

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

To: THE FILE

RE: DOCUMENT NUMBER K101514

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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:  
BD Directigen EZ™ RSV assay, K022133
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. The modification of the device consisted in the change from liquid control reagents to dry swabs controls. 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). Clinical and analytical performance/functionality remain unchanged from the previous device. The positive and negative liquid controls from the legally marketed device have been changed to a dry swab control formulation.
5. A **Design Control Activities Summary** which includes:
  - a) Risk Analysis conducted to identify expected hazards and risks associated with the planned modifications to the BD Directigen™ EZ RSV assay. Each hazard/risk identified in this analysis was evaluated according to the Risk Management procedure, and assigned a Risk Index level to indicate the severity of the hazard/risk and the probability of occurrence. Corrective Action(s) were then determined, if necessary, for each identified hazard/risk to mitigate the hazard/risk.
  - b) A declaration of conformity with design controls. The declaration of conformity includes:
    - i) A statement signed by Mr. Gregory P Payne, stating that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
    - ii) A statement signed by Mr. Gregory P Payne, stating that 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** 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 (or their preamendment) device.

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