

SPECIAL 510(k): Device Modification

To: THE FILE

RE: DOCUMENT NUMBER **K093116**

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:
RAMP Influenza A/B Assay (K071591)
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 **expanded reactivity table to include reactivity information for the 2009 H1N1 Influenza strain A/Swine NY/02/2009**. 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):
The RAMP Influenza A/B Assay was not modified in any way. Reactivity data for the 2009 H1N1 Influenza strain A/Swine NY/02/2009 was added to the analytical reactivity table. No performance characteristics were established, modified or removed based on this additional reactivity information. The intended use for this device remains the same.
5. **Design Control Activities Summary was provided:**
 - a) The method used for risk analysis for the RAMP Influenza A/B Assay is Failure Modes and Effects Analysis (FMEA).
 - b) Other than the analytical reactivity studies submitted, no further design verification tests or revisions to the risk management file were required as a result of this modification.
 - c) A declaration of conformity with design controls was provided. Sponsor provided a signed statement that:
 - i) 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) 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).**

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.