SPECIAL 510(k): Device Modification

To: **THE FILE** RE: **DOCUMENT NUMBER K100227**

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: **SAS FluAlert A Test (K041441).**

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED**. However there were modifications of the limitations for SAS FluAlert A Test (K041441).

3. The modification of the device consisted of expanded analytical sensitivity table to include reactivity information for the 2009 H1N1 Influenza strain (A/California/04/09). **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 SAS FluAlert A Test (K041441)
   b) Reactivity data for 2009 H1N1 was added to the analytical sensitivity table.
   c) Limitations were updated to reflect the reactivity data stating performance characteristics for detecting the 2009 H1N1 influenza virus directly from human specimens have not been established.
   d) Limitations for Influenza A test (K041441) in the CLIA waved and Moderate complexity product insert were updated for consistency.

5. **A declaration of conformity with design controls**.
   Sponsor provided a signed statement that:
   e) All verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
   f) 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**.
   Sponsor provided a signed Truthful and Accurate Statement, updated 510(k) summaries, 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.