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

To: THE FILE RE: DOCUMENT NUMBER K141859

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.
   CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel 510(k) number: K132508

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. A description of the device **MODIFICATION(S):**
   This change was for a revision of the package insert for the CDC Human Influenza Virus Real-Time RT_PCR Diagnostic Panel. Recently, additional assays have been included in the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel and cleared by FDA to accommodate the new influenza virus subtypes. The consumption of the various assays within the panel may be different since the prevalence of influenza virus types and subtypes vary from season to season. To address the variation in consumption, CDC will provide the users with an option to order different configurations of specific components of the panel to manage the supply of reagents more efficiently minimizing waste. The package insert was modified by removing information not related to the Influenza A/H5 Subtyping Kit. This modification will allow the CDC to provide the H5 Subtyping Kit separately from other components of the Diagnostic Panel (Influenza A/B Typing kit, Influenza A Subtyping Kit and Influenza B Lineage Genotyping Kit). No other text in the package insert has been added or modified. Different components of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel will be accompanied by revised labeling (package inserts) and the current submission is to clear the A/H5 subtyping kit.

   The **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed.**

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

   No changes were made to the intended use or physical characteristics of this test. The labelling changes did not include insertion or modification of any text, only text not relevant to the Influenza A/H5 Subtyping kit was removed.

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 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.