

SPECIAL 510(k): Device Modification

To: THE FILE

RE: DOCUMENT NUMBER K092423

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:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device:
Remel Xpect Flu A&B Test – K031565.
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 2009 H1N1 Influenza strain A/California/04/2009. 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):

Parameter	Device Additional Reactivity Claim Remel Xpect Flu A&B	Predicate Remel Xpect Flu A&B 510(k) Number K031565
INTENDED USE	Remel Xpect® Flu A&B is a rapid <i>in vitro</i> immunochromatographic test for the direct, qualitative detection of influenza A and influenza B viral antigens (nucleoprotein) from nasal wash, nasal swab, and throat swab specimens from symptomatic patients. The test is intended as an aid in the rapid diagnosis of influenza A and influenza B viral infections. Negative tests should be confirmed by cell culture.	Same
ANALYTE	Differentiated detection of influenza A & B nucleoprotein antigens	Same
TECHNOLOGY	Lateral flow immunochromatographic membrane assay	Same
SPECIMEN TYPE	Nasal wash, nasal swab, and throat swab specimens.	Same

5. **Design Control Activities Summary** which includes:

Not applicable.

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.