

SPECIAL 510(k): Device Modification

To: THE FILE

RE: DOCUMENT NUMBER K092223

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.
BinaxNOW Influenza A & B – K062109
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 strains: A/California/04/2009, A/Auckland/1/2009 and A/Auckland/3/2009. 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 Expanded Claim BinaxNOW Influenza A & B Test	Predicate BinaxNOW Influenza A & B Test 510(k) Number K062109
INTENDED USE	Detection of Influenza A & B antigens in nasopharynx swab, nasal swab and nasal wash/aspirate specimens	Same
ANALYTE	Differentiated detection of influenza A & B nucleoprotein antigens	Same
SPECIMEN TYPE	Nasopharyngeal swab, nasal swab and nasal wash/aspirate specimens	Same

5. **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
 - c) A declaration of conformity with design controls. The declaration of conformity should include:
 - i) A statement signed by the individual responsible, 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 the individual responsible, 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.

Not applicable to Class I devices.

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.