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

To: Quidel Corporation **RE:** K131606

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:

   Sofia® Influenza A+B FIA

   510(k) number: K112177

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. Description of the device **MODIFICATION(S):**

The modification presented in this special 510(k) consisted of **expanded reactivity table to include reactivity information for** the H7N9 influenza A virus. The firm tested the ability of the Sofia Influenza A+B FIA test to detect H7N9 influenza A virus. The virus used (A/Anhui/1/2013) was obtained from the Centers for Disease Control and Prevention as non-infectious beta-propiolactone inactivated virus. An LoD study was performed with the A/Anhui/1/2013 influenza strain at the following concentrations:

- 7.90×10^8 EID_{50}/mL
- 7.90×10^6 EID_{50}/mL
- 3.95×10^6 EID_{50}/mL
- 1.98×10^6 EID_{50}/mL
- 7.90×10^5 EID_{50}/mL
- 7.90×10^4 EID_{50}/mL

The LoD was determined to be 3.95×10^6 EID_{50}/ml. The Sofia Influenza A+B FIA test package insert has been updated to include the additional analytical reactivity information.

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

5. **Comparison Information**

Similarities

	Proposed Device	Predicate Device
Features	Sofia Influenza A+B FIA	Sofia Influenza A+B FIA
Read Results	Read results on instrument screen or print with optional printer	Read results on instrument screen or print with optional printer
Instrument	Sofia Analyzer	Sofia Analyzer
Calibrator	Yes – Calibration cassette and QC card provided	Yes – Calibration cassette and QC card provided
Specimen Types	Nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash	Nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash
Read Result Time	15 Minutes	15 Minutes
External Controls	Test kit contains positive and negative control swabs	Test kit contains positive and negative control swabs

Differences

The package insert has been updated to include detection of the A/Anhui/1/2013 H7N9 virus in the analytical reactivity information section:
A/Anhui/1/2013 - A - H7N9 - 3.95×10^6 EID_{50}/mL

Although this test has been shown to detect inactivated A/Anhui/1/2013 H7N9 virus cultured from positive human respiratory specimens, the performance characteristics of this device with clinical specimens that are positive for H7N9 influenza viruses have not been established. The Sofia Influenza A+B FIA test can distinguish between influenza A and B viruses, but it cannot differentiate influenza A subtypes.

6. **Design Control Activities Summary**:

Analytical Reactivity Testing was conducted as described in section 11, “Inclusivity and LoD for Influenza A H7/N9”.

A “Declaration of Conformity” statement was submitted for the manufacturing facility and validation activities and signed by the Senior Vice President of Clinical and Regulatory Affairs. The statements indicate that:

1. 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.
2. The validation activities, as required by the risk analysis, for the modification were performed by the designated individuals and the results demonstrated that the predetermined acceptance criteria were met.

In conclusion, based on the results of the analytical reactivity testing the modified labeling is truthful and accurate. The changes do not affect the performance of the test and it is therefore substantially equivalent to the current cleared test.

7. Truthful and Accurate Statement, a **510(k) Summary or Statement** and the **Indications for Use Enclosure.**

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 (or their preamendment) device.