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

To: THE FILE RE: DOCUMENT NUMBER K112199

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.

   xTAG Respiratory Viral Panel (RVP), K091667

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. There is a labeling change to add the xPONENT version of the TDAS software. This labeling change does not affect the intended use.

3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   This modification adds the assay specific software protocol (TDAS) that will allow the xTAG RVP kit to be used with xPONENT software. The fundamental scientific technology has not changed.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including labeling and a description of the parameters and settings in the new xPONENT version of the TDAS software as well as a wet test comparing the results of the old and new TDAS versions to assure that comparable results were generated.

   Table 5a: Results for xTAG RVP T-A: Analyzing 14 targets for each of 189 samples

Concordance Between:	**ABS / PRES calls**	**NEG Calls**	**POS calls**	**"No Call" Calls**	**Overall Calls**
IS (TDAS 1.11) and IS (TDAS 1.30)	348 / 348 = 100%	1815 / 1815 = 100%	166 / 166 = 100%	139 / 139 = 100%	2468 / 2468 = 100%
xPONENT (TDAS 1.30) and IS (TDAS 1.30)	348 / 348 = 100%	1814 / 1815 = 99.9%	166 / 166 = 100%	122 / 139 = 87.8%	2450 / 2468 = 99.3%

   •**PRES**: the recommended Internal / Run Control is detected (MFI ≥ 300)
   •**ABS**: the recommended Internal / Run Control is not detected (MFI < 300)
   •**No Call**: unable to determine presence or absence of the Internal / Run Control due to an assay-specific criterion not being met.
   •**POS:** the viral target is detected (i.e. analyte signal falls within the positive zone: MFI ≥300)
   •**NEG:** the viral target is not detected (i.e. analyte signal falls within the negative zone: MFI <150)

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

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.

   All Design Control Activities Summary documents were contained in the submission including the signed statements.