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

To: THE FILE RE: K081217

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This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II device requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device:

   HY●TEC Specific and Total IgE EIA (k941278) (*cover letter)*.

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** *(page 14)* along with the proposed labeling which includes instructions for use and package labeling *(page 38)*.

3. A description of the device **MODIFICATION(S),** *(cover letter)*, user's manual *(page 54)* in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**. **The changes included:**
   - Addition of a zero calibrator and software revisions to accommodate calculations

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device *(pages 15-16),* labeling, intended use, physical characteristics, and Design Control Activities *(pages 16, 101-107)* including: correlation with the original assay, analytical sensitivity and limit of detection, intra and inter assay precision, dilution linearity and stability of the zero calibrator.

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 *(page 95)*, 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 *(pages 17-19)*;
   c) A declaration of conformity with design controls *(page 109)*. 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.

6. A **Truthful and Accurate Statement** (page 7), a **510(k) Summary** *(page 21)* the **Indications for Use Enclosure** *(page 8)* **and FDA 3674: Certification of Compliance, under 42 U.S.C § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C § 282(j)** *(cover letter).*

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.