SPECIAL 510(k): Device Modification
OIR Review Memorandum

To: THE FILE **RE:** DOCUMENT NUMBER K131738

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Reserved Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary) for the ImmunoCAP Specific IgE Controls:

1. The name and 510(k) number of Phadia Us Inc. previously cleared device ImmunoCAP Specific IgE Controls, cleared under k051218.
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.
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 change was for packaging change for the ImmunoCAP Specific IgE Controls and minor changes to labeling. The packaging change is from one vial of allergen specific antibodies with control ranges provided for multiple allergens to three individual vials (ImmunoCAP Specific IgE Controls L/M/H), each with one allergen specific antibody at a pre-determined target range, available for purchase separately.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including *labeling, intended use and physical characteristics*.
5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) such as used to assess the impact of the modification on the device and its components, and the results of the analysis. *The Risk Analysis methods include failure modes, causes and consequences of hazards and are described in the document "Risk Management Summary, ImmunoCAP Specific IgE Controls L, M, H".*
   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 *(See the above-referenced Risk Management Summary document).*
   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.

6. A Truthful and Accurate Statement, a 510(k) Summary 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.