

## SPECIAL 510(k): Device Modification OIR Decision Memorandum

**To:** THE FILE

**RE:** K161899

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II 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. The ImmunoCAP Specific IgE and Total IgE assays were previously cleared under K051218 (for Specific IgE) and K133404 (for Total IgE).
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 directions for use for the ImmunoCAP Specific IgE and ImmunoCAP Total IgE assays on the cleared instruments.
3. A description of the device **MODIFICATION(S)** in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

**This change was for** the introduction of a new Reference Material (International Reference Preparation, IRP) for standardization of ImmunoCAP Specific and Total IgE assays, incorporating the 3rd WHO International Standard (3rd WHO IRP) for serum IgE (11/234).

No change of Intended Use/Indications for Use or fundamental scientific technology of the assay system has been made. No change of specifications or manufacturing methods for any assay reagents has been made.

Directions for Use for ImmunoCAP Specific and ImmunoCAP Total IgE will be updated to reflect the change. The update will be phased in over time. During a transition period Phadia intends to supply an intermediate version of labelling containing traceability information to either the old and new reference material..

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, Intended Use, physical characteristics, and traceability

The similarities and differences between the Predicate Device, ImmunoCAP Specific IgE as cleared under k051218, and the New Device, ImmunoCAP Specific IgE, are listed below.

### Similarities ImmunoCAP Specific IgE

<b>Similarities</b>		
Item	Predicate	Candidate
Intended Use	ImmunoCAP Specific IgE is an in vitro quantitative assay for the measurement of allergen specific IgE in human serum or plasma (EDTA or Na-Heparin). ImmunoCAP Specific IgE is to be used with instruments Phadia 100, Phadia 250, Phadia 1000, Phadia 2500 and Phadia 5000. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used in clinical laboratories.	Same
Sample matrix	Human serum or plasma (EDTA or Na-Heparin)	Same
Assay system and reagents	ImmunoCAP Specific IgE Conjugate, Calibrators, Controls, ImmunoCAP Allergens	Same

Similarities		
Item	Predicate	Candidate
Assay test principle	Immunofluorescence assay	Same
Instrumentation and Software	Phadia 100, Phadia 250, Phadia 1000 or Phadia 2500/ 5000, Phadia Information Data Manager	Same
Reporting of results	Quantitative, kUA/L	Same
Analytical sensitivity (LoD/LoQ)	0.1 kUA/L	Same

Differences		
Item	Predicate	Candidate
Traceability	The IgE calibrators are traceable (via an unbroken chain of calibrations) to the 2nd International Reference Preparation (IRP) 75/502 of Human Serum Immunoglobulin E from World Health Organization (WHO).	The IgE calibrators are traceable (via an unbroken chain of calibrations) to the 3rd International Reference Preparation (IRP) 11/234 of Human Serum Immunoglobulin E from World Health Organization (WHO)

The similarities and differences between the Predicate Device, ImmunoCAP Total IgE as cleared under k133404, and the New Device, ImmunoCAP Total IgE, are listed below.

**Similarities ImmunoCAP Total IgE**

Similarities		
Item	Predicate	Candidate
Intended Use	ImmunoCAP Total IgE is an in vitro test system for the quantitative measurement of circulating total IgE in human serum and plasma. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used in clinical laboratories. ImmunoCAP Total IgE is to be used with the instruments Phadia 100, Phadia 250, Phadia 1000,	Same
Sample matrix	Human serum or plasma (EDTA or Na-Heparin)	Same
Assay system and reagents	ImmunoCAP Total IgE Conjugate, Calibrators, Controls, Anti-IgE	Same
Assay test principle	Immunofluorescence assay	Same
Instrumentation and Software	Phadia 100, Phadia 250, Phadia 1000 or Phadia 2500/ 5000, Phadia Information Data Manager	Same
Reporting of results	Quantitative, kU/L	Same
Analytical sensitivity (LoD/LoQ)	2 kU/L	Same

Differences		
Item	Predicate	Candidate
Traceability	The IgE calibrators are traceable (via an unbroken chain of calibrations) to the 2nd International Reference Preparation (IRP) 75/502 of Human Serum Immunoglobulin E from World Health Organization (WHO).	The IgE calibrators are traceable (via an unbroken chain of calibrations) to the 3rd International Reference Preparation (IRP) 11/234 of Human Serum Immunoglobulin E from World Health Organization (WHO)

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

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.