

SPECIAL 510(k): Device Modification
OIVD Review Memorandum

To: **THE FILE**

RE: **k072661**

**ImmunoCAP™ Thyroglobulin ImmunoCAP
ImmunoCAP™ Thyroid Peroxidase ImmunoCAP
Autoimmunity Specific IgG Sample Diluent
ImmunoCAP™ Thyroglobulin IgG Antibodies Controls NLH
ImmunoCAP™ Thyroglobulin ImmunoCAP
ImmunoCAP™ Thyroid Peroxidase IgG Antibodies Controls NLH**

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. **UniCAP Thyroglobulin (k981559) and UniCAP Thyroid Peroxidase (k981930)**
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** (page 4) along with the proposed labeling which includes instructions for use, package labeling.
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**.

The change involves the following:

- Change of product name from UniCAP to ImmunoCAP
 - Change sample diluent which contains a blocking agent that binds unspecific binding antibodies
 - Option to use ImmunoCAP 100 as well as ImmunoCAP 250
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device included the following:

Topic	ImmunoCAP™ Thyroglobulin ImmunoCAP ImmunoCAP™ Thyroid Peroxidase ImmunoCAP Autoimmunity Specific IgG Sample Diluent ImmunoCAP™ Thyroglobulin IgG Antibodies Controls NLH ImmunoCAP™ Thyroid Peroxidase IgG Antibodies Controls NLH	UniCAP Thyroglobulin (k981559) UniCAP Thyroid Peroxidase (k981930)
Format	Thyroglobulin and Thyroid peroxidase controls NLH sold separately	Sample diluent and controls are kit components
Expected values (Data of Validation study included)	ImmunoCAP Thyroglobulin (n=100) <280 IU/mL ImmunoCAP TPO (n=100) <60 IU/mL	UniCAP Thyroglobulin (n=60) <220 IU/mL UniCAP TPO (n=60) <24 IU/mL
Suggested Cut-off	ImmunoCAP Thyroglobulin Normal <280 IU/mL Equivocal Zone 280-344 IU/mL Positive > 344 IU/mL ImmunoCAP TPO Normal <60 IU/mL Equivocal Zone 60-100 IU/mL Positive > 100 IU/mL	UniCAP Thyroglobulin Normal <172 IU/mL Equivocal Zone 172-344 IU/mL Positive > 344 IU/mL ImmunoCAP TPO Normal <60 IU/mL Equivocal Zone 60-100 IU/mL Positive > 100 IU/mL
Conversion Factor	Included in software	UniCAP Thyroglobulin

		1 mg _A /L = 86 IU/mL UniCAP TPO 1 mg _A /L = 10 IU/mL
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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. The risk analysis method used to assess the impact of the device modification was *Failure Mode and Effect Analysis (FMEA) procedure (Pages 1-8)*
- 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 attachment).
- 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 (page 38) 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 (page 38).

5. 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 modifications 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.