

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

To: THE FILE
RE: **k062516** Beckman Coulter Access Thyroglobulin Antibody II Assay on the Access
Immunoassay Systems

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II device (Beckman Coulter Access Thyroglobulin Antibody Assay (k012208) requiring 510(k). The following items are present and acceptable:

1. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** (page 1) along with the proposed labeling (package insert) which includes instructions for use (pages 29-39).
2. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, and user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
3. **These changes were for**
 - The name of the device was changed to Access Thyroglobulin Antibody II
 - The assay reagent pack configuration was changed from two reagent wells (R1 and R2) to a three well configuration (R1a, R1b, and R1c) with R1c containing a TRIS buffer.
 - EDTA plasma was added as an assay matrix.
 - Sample size was decreased from 20 μ L to 10 μ L.
 - The analytical sensitivity (limit of detection) was changed from 2.2 IU/mL to 0.9 IU/mL.
 - Revisions to the labeling were made to reflect these changes and to reflect results of design change validation studies.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, (pages 23-24 and 26-27); and
5. **A Design Control Activities Summary** which includes:
 - Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components: Failure Modes and Effects Analysis (FMEA), and the results of the analysis (page 25);
 - 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 (Table 3, page 25);
 - A declaration of conformity with design controls. The declaration of conformity should include:
 - 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 62), and

- 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 62).
6. A **Truthful and Accurate Statement** (page 59), a **510(k) Summary** (additional information received 10/4/06) and the **Indications for Use Enclosure** (additional information received 10/4/06)

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.