

SPECIAL 510(k): Device Modification  
OIVD Review Memorandum

To: **THE FILE**

RE: **k060176**

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**TheraTest EL-aCL™ screen and TheraTest EL-aCL™ IgM, IgG, IgA**

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. **TheraTest EL-ACA and TheraTest EL –aCL Test (k905301)**
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:**

- **Assay set-up**
  - **Separation of the package of one kit into two kits with a common Instruction booklet**
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device included the following:

Topic	TheraTest EL-aCL™ screen and TheraTest EL-aCL™ IgM, IgG, IgA (k060176) Modified Device	TheraTest EL-ACA and TheraTest EL – aCL Test (k905301)
<b>Intended Use</b>	Detection and measurement of autoantibodies in human serum directed against phospholipid cardiolipin	Same
<b>Reference ranges</b>	Addition of equivocal zone	No equivocal zone
<b>Packaging</b>	One kit for screening and another kit to be used for Ig class specific evaluation, sold separately	One kit for screening and Ig class specific evaluation
<b>Assay set-up</b> 1. Elimination of all specimen blank wells from the microplate	Entire plate coated with cardiolipin only	Wells are coated with blank and cardiolipin
2. Addition of specimen diluent into one cardiolipin blank well	Absorbance value in blank well containing specimen diluent subtracted from absorbance values of calibrator, controls and specimens	Absorbance value in blank wells subtracted from values obtained in the wells with human serum coated with cardiolipin
3. Calibrator	One level pre-diluted aCL IgM, IgG, IgA or aCL screen calibrator. Elimination of standard curve option	Lyophilized, one-level or optional serial dilution for a standard curve

**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 a Fault Tree Analysis (FTA) (page 4).

- 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 4-6).
- 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 (Attachment 3) 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 (Attachment 3).

**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 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.