

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

To: THE FILE RE: DOCUMENT NUMBER K092757

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- β GPI™ (IgM-IgG-gA) Test (k972790)
TheraTest EL- β GPI™ Scr Test (k973882)

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 (labeling changes are permitted as long as they do not affect the intended use).

There are no changes in Intended Use Indications for Use (Attachments 2a and b).

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 modifications were:

1. Replacing the β 2GPI calibrators with pre-diluted calibrators for the test kits listed above.
For the EL- β 2GPI™ (IgM-IgG-IgA): replaced the serum calibrator with pre-diluted calibrators for each isotype: β 2-GPI IgM Calibrator, β 2GPI IgG Calibrator, β 2-GPI IgA Calibrator.

For the EL- β 2GPI™ Scr, replaced the serum calibrator, which is a mix of three isotypes, with a pre-diluted calibrator, also a mix of three isotypes.

These changes are reflected in the Instruction Booklet, data sheet, box label, and calibrator labels for each test kit

2. Modifying the packaging of the EL- β 2GPI™ (IgM-IgG-IgA) kit. The kit will now consist of entire plates coated with β 2GPI only and entire plates consisting of blank wells. The operator will assemble antigen-coated wells, (printed with name), and blank wells, (printed with name) as required for testing. The change provides more flexibility for the operator. These changes will be reflected in the plate labels, box label and Instruction Booklet shown in Attachment 1. Also, some new catalog numbers will be created for individual components, and all existing customers will be notified of these changes.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, and physical characteristics

Similarities:

Feature	Modified Device
Intended Use	No Change
Fundamental Scientific Technology	No Change
Design Assay Detection	No Change
Performance	No Change

Differences:

For both the EL- β 2GPI™ (IgM, IgG, IgA) Test and the EL- β GPI™ Scr Test: replaced calibrators that required dilution by the user to Ready-to-use pre-diluted calibrators

For the EL- β 2GPI™ (IgM, IgG, IgA) Test, modified packaging to include entire plates coated with β 2GPI only and entire plates consisting of blank wells.

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

TheraTest Laboratories used Fault tree analysis and Failure Mode and Effect Analysis (FMEA) (page 5 of submission).

- 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

These are listed as part of the Fault tree analysis and failure mode and effect analysis (FMEA) (pages 5-8).

- 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.
See Attachment 3.

6. A **Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure.**

See Attachment 5 for Truthful and Accurate Statement, Attachment 4 for 510(k) Summary and Attachments 2a and 2b for Indications for use.

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.