

## **SPECIAL 510(k): Device Modification OIVD Review Memorandum**

**To:** THE FILE

**RE:** k043095

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Elecsys® AFP CalSet II

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. Elecsys® AFP CalSet (k981282)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** (page 5) 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**.

**These changes were:**

- change matrix type from buffer matrix to human serum matrix;
- change storage form from liquid to lyophilized; and
- change device name from **Elecsys AFP CalSet to Elecsys AFP CalSet II**

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device included labeling, intended use, physical characteristics, buffer matrix, storage form and stability of finished kit. Both devices have been standardized against the 1<sup>st</sup> IRP WHO reference standard 72/225.
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. The risk analysis method used to assess the impact of the device modification was a Failure Modes and Effects Analysis (FMEA) (page 26).
  - 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 (page 27).
  - 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 28) 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 28).

6. 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.