

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

**To:** THE FILE

**RE:** K041322

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VITROS Immunodiagnostic Products CEA Reagent Pack, Calibrators and Range Verifiers

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: VITROS Immunodiagnostic Products CEA Reagent Pack, Calibrators and Range Verifiers (k990943 and k990984)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED (page 12)** 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**.

**This change was for:**

- a change in the number of calibrators from 3 to 2;
  - calibrator #1 target value changed from 5 ng/mL to 3 ng/mL;
  - change in calibrator and range verifiers formulation from current base matrix (liquid BSA) to newborn calf serum; and
  - change in preservative in the calibrators and range verifiers from 2% Proclin 300 to 2% Kathon in the calibrators and range verifiers
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device included in addition to the changes listed in #3, labeling, intended use, and calibration range, sample type, antibodies, method principle, tracer, instrumentation, sample volume and incubation time and temperature.
  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 (**pages 18 and 19**). The risk analysis method used to assess the impact of the device modifications was a Failure Modes and Effects Analysis (FMEA).
    - 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 18 and 19**).
    - 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 10**), 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 11**).

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

The labeling for the modified subject devices has been reviewed to verify that the indication/intended use statements for the devices are 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 devices be determined substantially equivalent to the previously cleared devices.