

SPECIAL 510(k): Device Modification ODE Review Memorandum

To: THE FILE **RE:** DOCUMENT NUMBER K033780

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.) **K990977, SeraQuest EB VCA IgM assay.**
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. **The INDICATION/INTENDED USE and labeling have not changed from the cleared product insert. However, the sponsor did not submit any advertisements or promotional material.**
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.** **A change was for a modification of their antigen from Epstein-Barr viral capsid antigen, p18, on the coated wells to Epstein-Barr viral capsid antigen, gp125.**
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and **a Summary of technological characteristics (pp 19-20) between this device and the comparative device, Zeus EBV-VCA IgM ELISA.**
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 **This information has been provided.**
 - 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. **The sponsor's acceptance criterion is stated that they adhere to IAO/DIS 14971, Medical Devices – Application of Risk Management to Medical Devices. The sponsor states they have their own Risk Analysis procedures in place and have concluded that modification could have an effect on the performance characteristics of their device but should have no other impact on the device. Therefore, their verification and validation activities are based on in-house established performance characteristics.**
 - 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, 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.

The sponsor states in their declaration of conformity that their validation procedures consisted of comparing their device to a legally market device and their acceptance criterion consisted of an overall agreement of a 95% confidence interval of 87.7 to 96.4.
6. **A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices). These have been provided and are considered acceptable.**

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, **this device is determined substantially equivalent to the previously cleared (or their preamendment) device.**