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

To: THE FILE **RE:** DOCUMENT NUMBER k132076

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:

1. The Name and 510(k) number of the SUBMITTER'S previously cleared device: Lucor Confirmatory Reagent (k922156).
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: Proposed labeling i.e., vial and box labels were provided as Attachment 1 in k132076/S002 and the product insert was provided in k132076/S003.
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** modification of Lucor Confirmatory Reagent from lyophilized to a frozen format. The Submitter confirmed (k132076/S001, p.1) that there is no difference in the manufacturing and formulation process between the lyophilized and frozen format reagent except the additional step of reconstituting the lyophilized reagent, aliquoting and storage at -80^{o}C.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including labeling, intended use, stability and performance characteristics (k132076, p.4-5 of 10).
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: Risk analysis followed harmonized standard ISO 14971. Failure Mode and Risk Analysis (FMEA) method was applied (k132076, p.8 of 10). The Risk Management Plan, Risk Management Process and Preliminary Risk Analysis was provided in k132076/S001, pp.14-21.
   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. (k132076 p.8 of 10 and S001 pp.15-21).
   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. (k132076, p.7 of 10).
      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 (S002).
6. **A Truthful and Accurate Statement** (k132076 p.10 of 10), a **510(k) Statement** (k132076, p.9 of 10) and the **Indications for Use Enclosure** (k132076/S003).

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.