SPECIAL 510(k): Device Modification
OIR Decision Summary

To: THE FILE RE: DOCUMENT NUMBER K160922

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:
   a. K120663 - FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor α, Clone EP1, Ready-to-Use (Link)
   b. K130861 -FLEX Monoclonal Mouse Anti-Human Progesterone Receptor, Clone PgR 636, Ready-to-Use (Link)

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).

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 the addition of the new Dako PT Link PT200 as recommended equipment for automated epitope retrieval pre-treatment, and the addition of the Dako PT Link PT200 product code number in the Instructions For Use for the two Immunohistochemistry antibody assays.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including labeling, intended use, physical characteristics, and user-software interface.

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.
   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 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.