

**SPECIAL 510(K): DEVICE MODIFICATION
OIR DECISION SUMMARY**

510(k) Number: K181438

This 510(k) submission contains information/data on modifications made to the applicant's own class II or class I devices requiring 510(k). The following items are present and acceptable:

-
1. The name and 510(k) number of the applicant's previously cleared device.
K153394;
Diazyme Human Kappa (κ) Free Light Chain Assay
Diazyme Human Lambda (λ) Free Light Chain Assay
Diazyme Human Kappa/Lambda FLC Calibrator Set
Diazyme Human Kappa/Lambda FLC Control Set
 2. Applicant'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.
 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 to modify the Reference Range section in the package insert by adding the normal range of the Kappa to Lambda FLC ratio.
 4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including labeling, intended use, and physical characteristics.
 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 applicant'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 applicant 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.