

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

To: THE FILE

RE: DOCUMENT NUMBER K032287

---

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.
  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.
  3. A description of the device modifications, including package insert in sufficient detail to demonstrate that the fundamental scientific technology of the modified device has not changed. The modifications are the SYNCHRON Enzyme Validator Set has been value assigned for ALT, AMY, AST, CK, GGT and LD using the new 2002 IFCC reference method. Amylase (AMY) has been added to the list of analytes traceable to the IFCC reference method. There has been no change to the calibrator's formula. AMY was present in the predicate calibrator but was not value assigned until now.
- 
4. **Comparison Information** similarities to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, expected values, and method.
  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
    - 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.
  6. A **Truthful and Accurate Statement, a 510(k) Summary** and the **Indications for Use Enclosure.**

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.

