

SPECIAL 510(k): Device Modification
Review Memorandum

To: THE FILE

RE: DOCUMENT NUMBER K091980

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. ACL TOP (k073377)
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 **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**.
The modification: Adding an extra arm and hardware to interface with laboratory automation system (LAS)
4. **Comparison Information** to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics.
The difference: A Point-in-Space design solution is utilized where the patient sample remains under the control of the laboratory automated system. For sample analysis, an aliquot is aspirated by the ACL TOP 700 instrument and the primary container from the automation tract is not removed. The instrument software is modified to interface with an interface module computer, which controls the communications to the LAS system
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. *FMEA (Failure mode and effects analysis) see section 15*
 - 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. *(See section 15)*
 - c) A declaration of conformity (*see Section 8*) 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 device.