

SPECIAL 510(k): Device Modification OIR Decision Memorandum

To: THE FILE

RE: DOCUMENT NUMBER K160276

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: ACL TOP, K073377; K091980 (LAS model)
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 updating the instrument software to version 5.3.0 to support Windows 7 as the underlying operating system for ACL TOP family instruments (ACL TOP 700, ACL TOP 700 CTS, ACL TOP 700 LAS, ACL TOP 500 CTS, and ACL TOP 300 CTS).
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and assay methods. The difference is that the underlying operating system was changed from Windows XP to Window 7 in instrument software version 3.5.0. There are no other changes.
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. A high level risk analysis and a detailed software risk analysis with mitigation information were provided in the Pre-Market Risk Analysis Worksheet and Software Hazard Analysis Report. In conclusion, no patient or safety risks are introduced.
 - 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. Descriptions of verification and validation activities were provided for the ACL TOP family instrument application software at the unit, integration, and system levels. System level test protocols, including pass/fail criteria, and test results for PT and APTT assays were also provided.

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.