SPECIAL 510(k): Device Modification
OIR Decision Memorandum

To: THE FILE **RE:** DOCUMENT NUMBER K170314

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 AcuStar™, K083518
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**.

   This change was for an update of the operating system software from Windows XP to Windows 7 for the ACL AcuStar™ instrument.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, operating principle, hardware, data reduction software, fluidic design and test parameters.
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 Risk Analysis for the proposed change was conducted in accordance with ISO 14971 and SLT Risk Management Procedures. The applied risk analysis methods follow guidelines defined in AAMI TIR 45 (Guidance on the use of agile practices in the development of medical device software) to conciliate agile methods and techniques with 21 CFR 820.30, IS013485 and IEC 62304 requirements. The scope of the risk analysis covers patient, operator, environmental safety and the data protection from damage to its confidentiality, integrity or availability. Cybersecurity has been included in the ALBA Host Software risk analysis. It was concluded that the proposed change does not pose any additional risks and there is no impact on the safety or effectiveness of the product.

The labeling for the 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 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.