DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 03, 2017

Instrumentation Laboratory Co.
Ms. Nikita Malladi
Senior Regulatory Affairs Specialist
180 Hartwell Road
Bedford, MA 01730

Re: K170314
Trade/Device Name: ACL AcuStar™
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in-vitro coagulation studies
Regulatory Class: Class II
Product Code: JPA
Dated: January 31, 2017
Received: February 01, 2017

Dear Ms. Malladi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Leonthena R. Carrington -S

Lea Carrington, MS, MBA, MT(ASCP)
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

Device Name
ACL AcuStar™

Indications for Use *(Describe)*
Automated immunoassay analyzer designed specifically for in vitro diagnostic use in a clinical laboratory. The assay analysis is based on chemiluminescent technology. The system provides results for both direct measurements and calculated parameters.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

Instrumentation Laboratory
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# 510(k) Summary

The submission meets the criteria for a Special 510(k) under the FDA guidance "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications".

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| **Submitter's Information** | Instrumentation Laboratory (IL) Co.<br>180 Hartwell Road<br>Bedford, MA 01730, USA |

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| **Contact Person** | Nikita Malladi, Senior Regulatory Affairs Specialist<br>Phone: 781-674-3245<br>Fax: 781-861-4207<br>Email: nmalladi@ilww.com |

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| **Preparation Date** | January 31, 2017 |

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| **Device Trade Name** | ACL AcuStar™ |

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| **Regulatory Information** | Classification: Class II<br>Regulation No.: 21 CFR 864.5425<br>Common Name: System, Multipurpose For In Vitro Coagulation Studies<br>Panel: Hematology (81)<br>Product Code: JPA |

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| **Predicate Device** | ACL AcuStar: K083518 |

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| **Indications for Use / Intended Use** | The ACL AcuStar is an automated immunoassay analyzer designed specifically for *in vitro* diagnostic use in a clinical laboratory. The assay analysis is based on chemiluminescent technology. The system provides results for both direct measurements and calculated parameters. |

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| **Device Description** | The AcuStar is an automated, bench-top system for lab use that measures the analyte amount in samples by:<br>• Subjecting the sample to reagents that cause a reaction with an antigen or antibody in the sample.<br>• Placing the cuvettes in a controlled environment to let the reactants bind into a complex.<br>• Separating out the complex from unused reactants.<br>• Treating this complex with a chemical that produces light in proportion to the analyte concentration.<br>• Measuring the light output to determine the amount of antibodies or antigens that were in the sample. |

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| **Description of Modification** | This Special 510(k) is being submitted to update the operating system software from Windows XP to Windows 7 for the ACL AcuStar instrument. |

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| **Reason Submission Qualifies as Special 510(k)** | The submission meets the criteria for a Special 510(k) based on the following:<br>• No change in indications for use or intended use<br>• No change in operating principle<br>• No change to labeled performance claims<br>• No change to hardware<br>• No change to data reduction software<br>• No change to fluidic design<br>• No change to test parameters<br>• No change to calibration<br>• No change to quality control<br>• No change to consumables<br>• No change to reagents |

Comparison to Predicate Device (K083518):

Following is a description of the similarities and differences between the currently marketed ACL AcuStar Family (K083518) and ACL TOP Family with the Software 3.0.1 update:

| Item | Predicate Device (K083518) | Updated Device (with SW 3.0.1) |
|---|---|---|
| Trade Name | ACL AcuStar | Same |
| Indications for Use | ACL AcuStar is an automated immunoassay analyzer designed specifically for *in vitro* diagnostic use in a clinical laboratory. The assay analysis is based on chemiluminescent technology.<br>The system provides results for both direct measurements and calculated parameters. | Same |
| Physical Format | Single cartridge containing reagents | Same |
| Sample Type | Citrated Plasma or Serum (assay dependent) | Same |
| Dimensions | Height 54cm (21 ¼")<br>Width 87cm (34 ¼")<br>Depth 62cm (24 ½") | Same |
| Weight | 77.25 Kg (170.3 lbs) | Same |
| Methodology | Chemiluminescent technology | Same |
| Test Menu | Chemiluminescent immunoassays | Same |
| Software version | LR 10 | 3.0.1 |
| Operating System Software | Windows XP | Windows 7 |

**Conclusion:**

Based on the shared indications for use, operating principle, consumables, reagents, controls and calibrators, the ACL AcuStar with software v3.0.1 running on the Windows 7 operating system can be concluded to be substantially equivalent to the cleared and currently marketed predicate device, ACL AcuStar.