Section 5

510(k) Summary

5.1 Applicant Information

510(k) Owner:	Immucor, Inc.
Address:	3130 Gateway Drive Norcross, GA 30071
Phone:	(770)441-2051
Fax:	(770) 441-3807
Contact Person:	Patricia Lehman
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5.2 Device Information

Trade Name:	Echo Lumena™
Software Version:	2.1
Common Name:	Automated Blood Bank Analyzer
Classification Name:	Automated blood grouping and antibody test system
Product Code:	KSZ
Device Classification:	Class II
Regulation Number:	864.9175
Predicate Device:	Galileo Neo Automated Blood Bank System (BK170067)

5.3 Device Description and Intended Use:

The Echo Lumena is a microprocessor-controlled instrument designed to fully automate immunohematology *in vitro* diagnostic testing of human blood. The Echo Lumena automates test processing, result interpretation and data management functions. The Echo Lumena is designed to automate standard immunohematology assays using a micro-well strip-based platform. Assays include ABO and Rh (D) typing, detection/identification of IgG red blood cell antibodies, compatibility testing and red blood cell phenotyping.

The Echo Lumena uses software to drive its mechanics and data processing. The operator uses hardware in combination with the software to operate and maintain the Echo Lumena. All of Echo Lumena's functions are fully automated, including: sample and reagent handling, pipetting, incubation, washing, shaking, centrifugation, reading and interpretation of results.

The main instrument consists of the following modules:

- Sample and reagent loading bays
- Strip loading bay
- Incubators

- Pipetting system
- Transport system
- Washer
- Centrifuge
- Camera reader

The PC hardware consists of a keyboard, touch screen monitor, mouse, and handheld barcode scanner for entry of information into the Echo software

The Echo Lumena performs the following tests:

- ABO & RH Typing
- Antibody Screen
- Antibody Identification
- IgG Crossmatch
- Direct Antiglobulin
- Antigen Typing

5.4 Substantial Equivalence and Comparison to the Predicate Device:

Properties/Features/ Characteristics	Galileo Neo BK170067 (Predicate Device)	Echo Lumena (Proposed Device)	Comparison
Device Proprietary Name	Galileo Neo	Echo Lumena	N/A
Common Name	Automated Blood Bank Analyzer	Automated Blood Bank Analyzer	Same
Classification	Class II	Class II	Same
Regulation	21 CFR 864.9175	21 CFR 864.9175	Same
Intended Use	Automated immunohematology analyzer for in vitro diagnostic use	Automated immunohematology analyzer for in vitro diagnostic use	Same

Properties/Features/ Characteristics	Galileo Neo BK170067 (Predicate Device)	Echo Lumena (Proposed Device)	Comparison
Indications for Use	The Galileo Neo is a microprocessor-controlled instrument to fully automate immunohematology in vitro diagnostic testing of human blood. The NEO automates test processing, result interpretation and data management functions. The NEO is designed to automate standard immunohematology assays using a microplate-based platform. Assays include ABO grouping and Rh (D) typing, detection/identification of IgG red blood cell antibodies, compatibility testing, red blood cell phenotyping, antigen screening and infectious disease screening, such as cytomegalovirus (CMV). The antigen screening assays provide guidelines for the user to select antisera or dilute commercial blood grouping reagents as a mechanism to pre-screen for antigen negative blood units that can then be subjected to confirmation using a licensed method.	The Echo Lumena is a microprocessor-controlled instrument designed to fully automate immunohematology in vitro diagnostic testing of human blood. The Echo Lumena automates test processing, result interpretation, and data management functions. The Echo Lumena is designed to automate standard immunohematology assays using a micro-well strip-based platform. Assays include ABO and Rh (D) typing, detection/identification of IgG red blood cell antibodies, compatibility testing, and red blood cell phenotyping.	Equivalent (Except for CMV Testing)
Tests Performed	ABO & RH Typing Antibody Screen Antibody Identification IgG Crossmatch Direct Antiglobulin Antigen Typing CMV Antibody Testing	ABO & RH Typing Antibody Screen Antibody Identification IgG Crossmatch Direct Antiglobulin Antigen Typing	Equivalent
Test Reactions Reading	Digital Image Analysis	Digital Image Analysis	Same
User Interface	By Computer Workstation	By Computer Workstation	Same

Properties/Features/ Characteristics	Galileo Neo BK170067 (Predicate Device)	Echo Lumena (Proposed Device)	Comparison
System Security requires user passwords for access	Yes	Yes	Same
Testing performed on Plasma	Yes	Yes	Same
Testing performed on serum	Yes	Yes	Same
Barcode read on reagent and samples to confirm presence and location on the instrument	Yes	Yes	Same
Barcode read of reagent lot number and expiration date	Yes	Yes	Same
Manual entry of sample or reagent barcode requiring double blind entry	Yes	Yes	Same
Acceptable reagent vial size	10mL, 57mL	10 mL	Equivalent
Sample and reagent volume verification at aspiration	Yes	Yes	Same
Programmed to track volume or usage of each reagent vial or plate	Yes	Yes	Same
Prepares sample red cell suspension	Yes	Yes	Same
Multiple vials of same reagent can be loaded on instrument. When empty instrument switches to second vial	Yes	Yes	Same
Maintains Reagent Red Cell suspensions by agitation	Yes	Yes	Same
Walk away testing capability	Yes	Yes	Same
Instrument will discontinue operation if liquid waste is full	Yes	Yes	Same
Incubation duration and temperature are monitored	Yes	Yes	Same
Centrifuge performs at a consistent rpm range and duration	Yes	Yes	Same
Can be interfaced to laboratory information systems	Yes	Yes	Same

Properties/Features/ Characteristics	Galileo Neo BK170067 (Predicate Device)	Echo Lumena (Proposed Device)	Comparison
Camera Model/ module	Digi Camera	Lumenera Camera	Equivalent (change requires new assay interpretation algorithms and thresholds)
Software Operating System	Microsoft® Windows® 7	Microsoft® Windows® 7	Same
Software Version	2.2 (Rev.2)	2.1	Equivalent
Algorithm interpretation and thresholds	Interpretation by camera imaging	Interpretation by camera imaging	Equivalent

5.5 Performance Data and Testing – Non-Clinical

The Verification execution for Echo Lumena has been completed and the results have been found acceptable to confirm the Echo Lumena is meeting the design inputs.

- Each design input is mapped to at least one Verification Protocol – ensuring complete testing has been executed.
- The Verification Regression Analyses performed have provided the necessary evidence to support the iterative protocol execution process that has occurred over multiple software builds.
- The objective evidence obtained during protocol execution has demonstrated that all design input requirements have been met, or justification for exiting verification has been provided.
- The failures and anomalies that were discovered during Verification testing have been reconciled according to procedure.
- All documentation generated for the Verification activities of this system has been reviewed and approved.

5.6 Performance Data and Testing – Clinical

The results of the clinical study supported the conclusion that the IUO Echo instrument is able to generate results that are equivalent to the Galileo NEO instrument for the automated determination of ABO grouping and Rh (D) typing, phenotyping, detection/identification of Antibodies to red cells, compatibility testing and red blood cell phenotyping using in vitro diagnostic tests with the specified reagents for the instrument. The resolved results obtained on the two instruments were summarized below.

Reagent/ Assay	# of Samples	Overall Percent Agreement		Positive Percent Agreement		Negative Percent Agreement	
		% Agreement	95% one-side Lower CI	% Agreement	95% one-side Lower CI	% Agreement	95% one-side Lower CI
Anti-A (Murine Monoclonal) Series 1	5962	99.4%	99.2%	100.0%	99.9%	99.9%	99.8%
Anti-B (Murine Monoclonal) Series 3	5962	99.8%	99.7%	100.0%	99.7%	100.0%	99.9%
Anti-D (Monoclonal Blend) Series 4	5962	99.7%	99.6%	100.0%	99.9%	99.1%	98.3%
Anti-D (Monoclonal Blend) Series 5	5322	99.8%	99.7%	100.0%	99.6%	99.6%	98.9%
Referencells A1	5322	99.2%	98.9%	99.2%	98.9%	99.1%	98.7%
Referencells B	5322	99.4%	99.2%	99.5%	99.3%	98.7%	97.8%
Anti-C (Monoclonal) Gamma-clone	1995	99.1%	98.7%	98.9%	98.2%	100.0%	99.6%
Anti-c (Monoclonal) Series 1	1995	99.8%	99.5%	99.8%	99.4%	100%	99.2%
Anti-E (Monoclonal) Gamma-clone	1995	99.0%	98.5%	97.8%	96.5%	100.0%	99.8%
Anti-e (Monoclonal) Gamma-clone	1995	100.0%	99.9%	100.0%	99.8%	100.0%	99.2%
Anti-K (Monoclonal) Gamma-clone	1086	100.0%	99.7%	100.0%	97.6%	100.0%	99.7%
Weak D	687	99.4%	98.7%	100%	86.1%	99.9%	99.3%
Crossmatch	602	100.0%	99.5%	100.0%	99.0%	100.0%	99.0%
DAT - Random	400	98.5%	97.1%	75.0%	24.9%	99.0%	97.7%
DAT - Contrived	300	100.0%	99.0%	100.0%	99.0%	N/A	N/A
Screen – Random	3153	98.5%	98.1%	85.7%	73.7%	98.9%	98.6%
Screen - Characterized	300	99.7%	98.4%	99.7%	98.4%	N/A	N/A
Ready ID - Characterized	300	100.0%	99.0%	100.0%	99.0%	N/A	N/A

5.7 Conclusion

The clinical and non-clinical performance data demonstrates substantial equivalence in terms of its safety, reproducibility, design, and indications for use.