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:	Galileo Echo®
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 Galileo Echo® is a microprocessor-controlled instrument designed to fully automate immunohematology *in vitro* diagnostic testing of human blood. The Galileo Echo automates test processing, result interpretation and data management functions. The Galileo Echo 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 Galileo Echo uses software to drive its mechanics and data processing. The operator uses hardware in combination with the software to operate and maintain the Galileo Echo. All of Galileo Echo'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 Galileo Echo 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)	Galileo Echo (Proposed Device)	Comparison
Device Proprietary Name	Galileo Neo	Galileo Echo	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)	Galileo Echo (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 Galileo Echo is a microprocessor-controlled instrument designed to fully automate immunohematology in vitro diagnostic testing of human blood. The Galileo Echo automates test processing, result interpretation, and data management functions. The Galileo Echo 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 (Except for CMV testing)
Test Reactions Reading	Digital Image Analysis	Digital Image Analysis	Same
User Interface	By Computer Workstation	By Computer Workstation	Same
System Security requires user passwords for access	Yes	Yes	Same
Testing performed on Plasma	Yes	Yes	Same

Properties/Features/ Characteristics	Galileo Neo BK170067 (Predicate Device)	Galileo Echo (Proposed Device)	Comparison
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

Properties/Features/ Characteristics	Galileo Neo BK170067 (Predicate Device)	Galileo Echo (Proposed Device)	Comparison
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
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 Galileo Echo (v.2.0) has been completed and the results have been found acceptable to confirm the Galileo Echo 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

Method comparison studies were performed at four external clinical sites. Specimens were tested on Galileo Echo and Galileo Neo. Specimens that gave initial equivocal (?) test well results were retested on the analyzer that gave the initial equivocal results. Test results were evaluated for agreement between analyzers. Combined results from all sites are summarized in the following tables:

Note: Agreement between methods does not indicate which method is correct.

Reagent/Assay	# of Samples Analyzed	Overall		PPA		NPA	
		Overall Percent Agreement	Lower 95% Confidence Interval	Positive Percent Agreement	Lower 95% Confidence Interval	Negative Percent Agreement	Lower 95% Confidence Interval
Anti-A (Murine Monoclonal) Series 1	5682	99.8%	99.7%	100.0%	99.9%	99.9%	99.8%
Anti-B (Murine Monoclonal) Series 3	5682	99.7%	99.6%	100.0%	99.7%	100.0%	99.9%
Anti-D (Monoclonal Blend) Series 4	5682	99.7%	99.5%	100.0%	99.9%	98.5%	97.5%
Anti-D (Monoclonal Blend) Series 5	5044	99.8%	99.6%	100.0%	99.9%	100.0%	99.6%
Referencells A1	5044	98.6%	98.2%	99.3%	99.0%	97.4%	96.7%
Referencells B	5044	99.1%	98.9%	99.6%	99.4%	96.8%	95.6%
Anti-C (Monoclonal) Gamma-clone	1993	99.1%	98.6%	98.9%	98.3%	100.0%	99.6%
Anti-c (Monoclona) Series 1	1993	99.7%	99.4%	99.8%	99.4%	99.7%	98.7%

Reagent/Assay	# of Samples Analyzed	Overall		PPA		NPA	
		Overall Percent Agreement	Lower 95% Confidence Interval	Positive Percent Agreement	Lower 95% Confidence Interval	Negative Percent Agreement	Lower 95% Confidence Interval
Anti-E (Monoclonal) Gamma-clone	1993	98.9%	98.4%	97.4%	96.1%	100.0%	99.8%
Anti-e (Monoclonal) Gamma-clone	1993	100.0%	99.9%	100.0%	99.9%	100.0%	96.9%
Anti-K (Monoclonal) Gamma-clone	1086	100.0%	99.7%	100.0%	97.6%	100.0%	99.7%
Weak D	663	99.4%	98.6%	100%	86.1%	99.8%	99.3%
IgG Crossmatch	602	100.0%	99.5%	100.0%	99.0%	100.0%	99.0%
DAT – Random samples	400	98.0%	96.48%	75.0%	24.9%	98.5%	97.0%
DAT – Contrived samples	300	100.0%	99.0%	100.0%	99.0%	N/A	N/A
Screen – Random samples	3166	98.1%	97.7%	90.0%	78.6%	98.7%	98.3%
Screen – Characterized samples	299	100%	99.0%	100.0%	99.0%	N/A	N/A
Ready ID – Characterized samples	299	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.