Section 5

510(k) Summary

5.1 Applicant Information

510(k) Owner:	Immucor, Inc.
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5.2 Device Information

Trade Name:	NEO Iris™
Software Version:	3.0
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 NEO Iris™ is a microprocessor-controlled instrument to fully automate immunohematology in vitro diagnostic testing of human blood. The NEO Iris automates test processing, result interpretation and data management functions. The NEO Iris 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 and antigen screening.

The NEO Iris is for in vitro diagnostic use.

The NEO Iris is a closed system and can only be used with specified Immucor products.

The NEO Iris is a robotic instrument programmed to move microplates, liquid reagent fluids, and blood sample fluids to different bays and processing areas for a given assay in the correct sequence. Such bays and areas include incubator bays, the microplate washing station, the centrifuge, and the reader.

The NEO Iris plate reader uses (b) (4) cameras to capture an image of the microplate from underneath. The NEO Iris software calculates a reaction value for each well based on a multi feature image analysis. The NEO Iris then assigns a result and interpretation to the wells based on predefined criteria associated with the calculated reaction value. Some assay protocols require multiple test wells for a given blood sample interpretation, such as ABO and Rh (D) typing.

The NEO Iris uses software to drive its mechanics and data processing. The operator uses hardware in combination with the software to operate and maintain the NEO Iris.

5.4 Substantial Equivalence and Comparison to the Predicate Device:

Properties/Features/ Characteristics	Galileo Neo BK170067 (Predicate Device)	NEO Iris (Proposed Device)	Comparison
Device Proprietary Name	Galileo Neo	NEO Iris	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)	NEO Iris (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 NEO Iris is a microprocessor-controlled instrument to fully automate immunohematology in vitro diagnostic testing of human blood. The NEO Iris automates test processing, result interpretation and data management functions. The NEO Iris 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 and antigen screening.	Equivalent
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 CMV Antibody Testing	Same
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
Testing performed on serum	Yes	Yes	Same

Properties/Features/ Characteristics	Galileo Neo BK170067 (Predicate Device)	NEO Iris (Proposed Device)	Comparison
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, 57mL	Same
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
Software Operating System	Microsoft® Windows® 7	Microsoft® Windows® 7	Same
Algorithm interpretation and thresholds	Interpretation by camera imaging	Interpretation by camera imaging	Same

5.5 Performance Data and Testing – Non-Clinical

The Verification execution for the NEO Iris has been completed and the results have been found acceptable to confirm the NEO Iris 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 software builds.
- The objective evidence obtained during protocol execution has demonstrated that all design input requirements have been met, or justification for verification results has been provided.
- The failures and anomalies that were discovered during Verification testing have been reconciled.
- 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 NEO Iris is able to generate results that are equivalent or better than 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 Analyzed	Positive Percent Agreement		Negative Percent Agreement	
		PPA	95% one-sided LCL	NPA	95% one-sided LCL
Anti-A (Murine Monoclonal) Series 1	3954	100.0%	99.8%	100.0%	99.9%
Anti-B (Murine Monoclonal) Series 3	3952	100.0%	99.5%	100.0%	99.9%
Anti-A,B (Murine Monoclonal) Series 1	3953	99.9%	99.8%	100.0%	99.9%
Anti-D (Monoclonal Blend) Series 4	3953	100.0%	99.9%	100.0%	99.2%
Anti-D (Monoclonal Blend) Series 5	2945	99.9%	99.8%	100.0%	99.0%

Reagent/Assay	# of Samples Analyzed	Positive Percent Agreement		Negative Percent Agreement	
		PPA	95% one-sided LCL	NPA	95% one-sided LCL
Referencells A1	2945	99.8%	99.6%	100.0%	99.7%
Referencells B	2944	99.9%	99.8%	99.8%	98.9%
Anti-C (Monoclonal) Gamma-clone	2124	100.0%	99.8%	100.0%	99.6%
Anti-c (Monoclonal) Series 1	2127	99.9%	99.7%	100.0%	99.3%
Anti-E (Monoclonal) Gamma-clone	2115	100.0%	99.6%	100.0%	99.8%
Anti-e (Monoclonal) Gamma-clone	2129	100.0%	99.9%	100.0%	97.0%*
Anti-K (Monoclonal) Gamma-clone	2045	100.0%	98.2%*	99.9%	99.7%
Weak D	418	100.0%	74.1%*	100.0%	99.3%
IgG_XM	604	100.0%	99.0%	100.0%	99.0%
DAT (Random)	308	100.0%	*	100.0%	99.0%
DAT (Contrived)	300	100.0%	99.0%	N/A	
Capture-CMV (Donor Screening)	1248	99.8% Sensitivity	99.1%†	98.7% Specificity	97.4%†
Pool_Cell (Random)	1857	100.0%	74.1%*	99.8%	99.6%
Pool_Cell (Well Characterized)	283	98.6%	96.8%	N/A	
3_Cell (Random)	1789	72.7%*	53.2%*	99.7%	99.3%
3_Cell (Well Characterized)	275	100.0%	98.9%	N/A	
Ready ID (Well Characterized)	282	100.0%	98.9%	N/A	

*Low frequency in population tested. †95% two-sided LCL

5.7 Conclusion

The clinical and non-clinical performance data demonstrate substantial equivalence in terms of the NEO Iris safety, reproducibility, design, and indications for use.