7.0 510(k) Summary

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510(k) Owner

Immucor, Inc.
3130 Gateway Drive
Norcross, Georgia 30071
Establishment Registration Number: 1034569

Contact Information

Name of Contact:	Steven Appel
Phone Number:	770-440-2051
Fax Number:	770-242-8930

Device Name

Trade/Device Name:	NEO Iris®
Common Name:	Automated Blood Bank Analyzer
Classification Name:	Automated blood grouping and antibody test system
Unique Device Identifier (UDI):	10888234002321

Device Class

Regulatory Class:	II
Product Code:	KSZ
Regulation Number:	21CFR§864.9175
Classification Advisory Committee:	Hematology
Review Advisory Committee:	Hematology

Predicate Device Information

Trade/Device Name:	ORTHO VISION™ Max Analyzer
Clearance:	BK160058 (cleared October 21, 2016)

Device Description

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 as incubator bays, the microplate washing station, the centrifuge, and the reader. The NEO Iris plate reader uses CMOS 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.

All of NEO Iris' functions are fully automated, including: sample and reagent handling, pipetting, incubation, washing, shaking, centrifugation, reading and interpretation of results. Automated process controls and error detection mechanisms significantly reduce or eliminate opportunities for user error and invalidate suspect results.

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.

Technological Comparison to Predicate Device

Below is a summary of the technological characteristics of modified NEO Iris (proposed device) compared to the predicate device ORTHO VISION™ Max Analyzer (BK160058).

Characteristic / Feature	Predicate	New/Modified Device
Trade/Device Name	ORTHO VISION™ Max Analyzer (BK160058)	NEO Iris
Indication For Use		
Automated immunohematology instrument for in vitro diagnostic use	ORTHO VISION™ Max Analyzer is an instrument designed to automate in vitro immunohematology testing of human blood utilizing ID-MTS™ gel card technology. ORTHO VISION™ Max Analyzer automates test processing functions including liquid pipetting, reagent handling, incubation, centrifugation, reaction grading and interpretation and data management requirements using cards and digital image processing. ORTHO VISION™ Max Analyzer can be used as a standalone instrument or interfaced to the customer's Laboratory Information System (LIS).	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.
Regulatory		
Product Code	KSZ	KSZ
Regulation Number	21CFR§864.9175	21CFR§864.9175
Specimen Types		
Plasma	YES	YES
Serum	YES	YES
Red Cells	YES	YES
Assay Types		
ABO/RH	YES	YES
Antibody Detection/Identification	YES	YES
Crossmatch	YES	YES
Direct Antiglobulin Test	YES	YES
Antigen Testing	YES	YES
QC Testing	YES	YES
Serial Dilution for Titration Studies	Tested with user-selected red blood cells (e.g. A1, A2, B, Fy(a+), etc. Reagent Red Blood Cells)	ABO Titration: Tested with A1, A2 and B Reagent Red Blood Cells Non-ABO Titration: Tested with user-selected Reagent Red Blood Cells (Panoscreen®)

Clinical Performance

Automated ABO Titration Assay

The objective of the clinical study was to demonstrate whether the results obtained by testing the samples with the ABO Titration Assays on the NEO Iris were within 2 doubling dilutions when compared to the ABO Automated Titration Assays on the Galileo Neo. The study was performed at two (2) external sites and one (1) internal site. The external sites were representative of blood collection establishments, hospital-based transfusion services, and/or clinical laboratories. The internal site testing included both donor and patient specimens.

All samples were tested using the Automated ABO titration assays on the NEO Iris and the Automated ABO titration assays on the Galileo Neo. All discordant samples were manually diluted and tested on the Galileo Neo. After testing was completed, all assays met the acceptance criteria of 100% agreement that the titer results were within ±2 doubling dilutions, except for the IgM anti-B (TMB) assay and the Low Titer IgG anti-B (LTGB). For the TMB assay, one sample was discordant with an overall percentage agreement of 98.95% (n=94, 95.10% LCI). For the LTGB assay, one sample was discordant for an overall percent agreement of 98.97% (n=97, 95.20% LCI). The two samples were QNS for any additional testing. Although the TMB and TLGB assays did not meet the acceptance criteria of 100% agreement within ±2 doubling dilutions due to discordant sample results, the reproducibility and overall percent agreement for the assays are still clinically acceptable.

Test results were compared for agreement between the automated ABO titration assays for NEO Iris and the Automated ABO titration assays Galileo NEO.

Summary of Initial Results from Method Comparison Testing							
Method Comparison Summary of All Assay Results		Equal or within ±1 Doubling Dilution			Equal or within ±2 Doubling Dilutions		
Assay	N	n	Agreement (%)	LCI* (%)	n	Agreement (%)	LCI* (%)
TMA1	102	84	82.35	74.96	99	97.06	92.57
TMA2	102	91	89.22	82.78	100	98.04	93.96
TMB	95	84	88.42	81.56	93	97.90	93.52
TLGA1	98	89	90.82	84.52	98	100.00	96.31
THGA1	22	21	95.46	80.19	22	100.00	84.56
TLGA1/THGA1	102	90	88.24	81.64	102	100.00	96.45
TLGA2	102	95	93.14	87.50	102	100.00	96.45
TLGB	97	86	88.66	81.93	96	98.97	95.20
THGB	13	13	100.00	75.29	13	100.00	75.29
TLGB/THGB	98	87	88.78	82.11	97	98.98	95.25

*Agreement at the 95% one-sided lower confidence interval
Discordant samples were manually diluted and tested by a reference method. Resolved results are presented below.

Summary of Resolved Results from Method Comparison Testing							
Method Comparison Summary of All Assay Results		Equal or within ±1 Doubling Dilution			Equal or within ±2 Doubling Dilutions		
Assay	N	n	Agreement (%)	LCI* (%)	n	Agreement (%)	LCI* (%)
TMA1	102	87	85.29	78.26	102	100.00	96.45
TMA2	102	93	91.18	85.11	102	100.00	96.45
TMB	95	85	89.47	82.80	94	98.95	95.10
TLGA1	98	89	90.82	84.52	98	100.00	96.31
THGA1	22	21	95.46	80.19	22	100.00	84.56
TLGA1/THGA1	102	90	88.24	81.64	102	100.00	96.45
TLGA2	102	95	93.14	87.50	102	100.00	96.45
TLGB	97	86	88.66	81.93	96	98.97	95.20
THGB	13	13	100.00	75.29	13	100.00	75.29
TLGB/THGB	98	87	88.78	82.11	97	98.98	95.25

* Agreement at the 95% one-sided lower confidence interval

The reproducibility of the ABO Titration Assays was evaluated at two (2) external sites and at Immucor, Inc. as an internal site. Each site tested three (3) samples per assay, representing low, medium and high titers covering the range of the assay. The samples were tested in triplicate per run, two (2) runs per day, for five (5) nonconsecutive days.

Reproducibility Summary of All Assay Results		Equal or within ±1 Doubling Dilution			Equal or within ±2 Doubling Dilutions		
Assay	N	n	Agreement (%)	LCI** (%)	n	Agreement (%)	LCI** (%)
TMA1	270	250	92.6	89.42	270	100	98.64
TMA2	270	270	100	98.64	270	100	98.64
TMB	270	270	100	98.64	270	100	98.64
TLGA1/THGA1	264	200	75.8	71.02	264	100	98.61
TLGA1*	174	147	84.5	79.24	174	100	97.97
THGA1	90	53	58.9	49.68	90	100	95.98
TLGA2*	266	203	76.3	71.36	266	100	98.62
TLGB/THGB	270	259	95.9	93.35	270	100	98.64
TLGB	180	169	93.9	90.09	180	100	97.97
THGB	90	90	100	95.98	90	100	95.98

* Six (6) TLGA1 and four (4) TLGA2 initial and repeat results were invalid due to inconsistent grading and not included in agreement calculations

** Agreement at the 95% one-sided lower confidence interval

Automated Non-ABO Titration Assay

The objective of the clinical study was to verify that titer results determined with the non-ABO automated titration assays on NEO Iris were within ±2 doubling dilutions when compared to manually prepare doubling dilutions tested on the same instrument. The study was performed at two (2) external sites and one (1) internal site. The external sites were representative of blood collection establishments, hospital-based transfusion services, and/or clinical laboratories.

The acceptance criterion was 100% agreement that the titer results determined by NEO Iris automated titration assays are within ±2 doubling dilution(s) from manually prepare dilutions tested on the same instrument. In the method comparison study, 65 samples were analyzed and all had titration results on the NEO Iris within two doubling dilutions of the manually prepared dilutions.

For non-ABO Titration assays that use Panoscreen I, II, III (TP_P assays), 100% of the titer results were within two doubling dilutions of the titer results determined by manually prepared dilutions tested on modified crossmatch assay. For non-ABO Titration assays that use Panoscreen EXTEND cells (TP_E assays), 100% of the titer results were within two doubling dilutions of the titer results determined by manually prepared dilutions tested on modified crossmatch assay.

Specimens were tested on NEO Iris. Test results were compared for agreement between the automated titer assays and results for manually prepared dilutions.

Comparison Non-ABO Titrations vs. Manual Doubling Dilutions	Equal or within ±1 Doubling Dilution			Equal or within ±2 Doubling Dilutions		
N	n	Agreement (%)	LCI* (%)	n	Agreement (%)	LCI* (%)
66	62	93.9	86.7	100	100	95.6

* Agreement at the 95% one-sided lower confidence interval

The reproducibility of the Non-ABO Titration Assays was evaluated at two (2) external sites and at Immucor, Inc. as an internal site. Each site tested three (3) samples per assay, representing low, medium and high titers covering the range of the assay. The samples were tested in triplicate per run, two (2) runs per day, for five (5) nonconsecutive days.

Reproducibility Summary of All Assay Results		Equal or within ±1 Doubling Dilution			Equal or within ±2 Doubling Dilutions		
Assay	**N**	**n**	**Agreement (%)**	**LCI* (%)**	**n**	**Agreement (%)**	**LCI* (%)**
T_IgG_P1	90	90	100	95.9	90	100	95.9
T_IgG_P2	90	90	100	95.9	90	100	95.9
T_IgG_E2	90	90	100	95.9	90	100	95.9
T_IgG_E5	90	90	100	95.9	90	100	95.9

* Agreement at the 95% one-sided lower confidence interval

Basis for Claim of Substantial Equivalence

The modified NEO Iris is substantially equivalent to the predicate device in a comparison of the technological characteristics of both instruments. Notably both may be used to perform automated Serial Dilutions for Titration Studies using Reagent Red Blood Cells.

Additionally, in clinical performance evaluations the modified NEO Iris has been demonstrated to meet the acceptance criteria whereby Automated Titration assay results were within two (2) doubling dilution(s) when compared to the titer results determined by reference method except for the IgM anti-B (TMB) assay and the Low Titer IgG anti-B (LTGB). For the TMB assay, one sample was discordant with an overall percentage agreement of 98.95% (n=94, 95.10% LCI). For the LTGB assay, one sample was discordant for an overall percent agreement of 98.97% (n=97, 95.20% LCI). The two samples were QNS for any additional testing. Although the TMB and TLGB assays did not meet the acceptance criteria of 100% agreement within ±2 doubling dilutions due to discordant sample results, the reproducibility and overall percent agreement for the assays are still clinically acceptable.