7.0 510(k) Summary

Date Prepared

October 6, 2020

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:	Galileo NEO®
Common Name:	Automated Blood Bank Analyzer
Classification Name:	Automated blood grouping and antibody test system
Unique Device Identifier (UDI):	10888234001041

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:	NEO Iris
Clearance:	BK200474 (cleared June 12, 2020) and BK180243 (cleared November 7, 2018)

Device Description

The Galileo NEO, or NEO, is a microprocessor-controlled instrument to fully automate immunohematology in vitro diagnostic testing of human blood. The Galileo NEO automates test processing, result interpretation and data management functions. The Galileo 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 and antigen screening. The Galileo NEO is for in vitro diagnostic use.

The NEO 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 plate reader uses CCD cameras to capture an image of the microplate from underneath. The NEO software calculates a reaction value for each well based on a multi-feature image analysis. The NEO 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 uses software to drive its mechanics and data processing. The operator uses hardware in combination with the software to operate and maintain the NEO.

All of NEO's 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.

The upgrades to the Galileo NEO will bring the instrument up to the design and performance specifications of the NEO Iris by replacement of camera and software components; with this upgrade in place the two instruments are technologically and functionally identical. Upgrades to the Galileo NEO consist of the following modifications (which are performed by Immucor Service Technicians at the Customer site):

- The Digi camera module is replaced with an IDS camera module
- Galileo NEO software is replaced with NEO Iris Install Set 3.0.1.0 U software and configuration files
- Installation of Galileo NEO versions of the files OiBxEngl.dll and GalileoLogo.bmp to preserve Galileo NEO branding in the User Interface and on Reports

Intended Use

The Galileo NEO is a microprocessor-controlled instrument to fully automate immunohematology in vitro diagnostic testing of human blood. The Galileo NEO automates test processing, result interpretation and data management functions. The Galileo 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 and antigen screening. The Galileo NEO is for in vitro diagnostic use.

Technological Comparison to Predicate Device

The NEO Iris is itself a factory upgrade to the Galileo NEO design in which the Digi camera module and instrument software of the previously-cleared Galileo NEO was replaced with the IDS camera module and software. The upgraded Galileo NEO will contain the exact same IDS camera and software used in the NEO Iris.

The upgraded Galileo NEO is based upon the same design as the NEO Iris; that is, a Galileo Neo upgraded with the new IDS CMOS camera module and software version 3.xxx. The two instruments are not only equivalent, they are identical; the only differences are model name, the exterior colors of the instruments, and whether the software indicates the device name as NEO Iris or Galileo NEO.

Below is a summary of the technological characteristics of the modified/upgraded Galileo NEO compared to the predicate device (NEO Iris).

Characteristic / Feature	Predicate	New/Modified Device	Comparison
Trade/Device Name	NEO Iris / BK200474 (cleared June 12, 2020) BK180243 (cleared November 7, 2018)	Galileo NEO	
Technology			
Camera	IDS camera module	IDS camera module	Identical
Software	NEO Iris Install Set 3.0.1	NEO Iris Install Set 3.0.1	Identical
Indication For Use			
Automated immunohematology instrument for in vitro diagnostic 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 Galileo NEO is a microprocessor-controlled instrument to fully automate immunohematology in vitro diagnostic testing of human blood. The Galileo NEO automates test processing, result interpretation and data management functions. The Galileo 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 and antigen screening. The Galileo NEO is for in vitro diagnostic use.	Identical (except for instrument name)
Regulatory			
Product Code	KSZ	KSZ	Identical
Regulation Number	21CFR§864.9175	21CFR§864.9175	Identical
Specimen Types			
Plasma	YES	YES	Identical
Serum	YES	YES	Identical
Red Cells	YES	YES	Identical
Assay Types			
ABO/RH	YES	YES	Identical
Antibody Detection/Identification	YES	YES	Identical
Crossmatch	YES	YES	Identical
Direct Antiglobulin Test	YES	YES	Identical
Antigen Testing	YES	YES	Identical
QC Testing	YES	YES	Identical
Serial Dilution for Titration Studies	YES	YES	Identical

Clinical Performance

The clinical performance study results provided below have been previously reviewed by FDA under Premarket Notification BK180243 (cleared November 7, 2018). Specimens were tested on the original Galileo Neo and NEO Iris. Test results were evaluated for agreement between analyzers.

The results in the table below demonstrate that the NEO Iris and the upgraded Galileo NEO instruments are able to generate results that are equivalent or better than the original Galileo NEO instrument for the automated determination of ABO grouping and Rh (D) typing, 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 are summarized in the table 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%
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	
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.

Automated ABO Titration Assay

The clinical performance study results provided below have been previously reviewed by FDA under Premarket Notification BK200474 (cleared June 12, 2020). 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 clinical performance study results provided below have been previously reviewed by FDA under Premarket Notification BK200474 (cleared June 12, 2020). 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, 66 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	66	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 non-clinical verification, validation and regression analysis studies presented in **Section 18.0** of this Application demonstrate a technological, functional and performance equivalence between the NEO Iris instrument and the upgraded Galileo NEO instrument.

There are no differences between the proposed and the predicate device with respect to indications for use or technology. The NEO Iris is itself a factory upgrade to the Galileo NEO design in which the Digi camera module and instrument software of the previously-cleared Galileo NEO was replaced with the exact same IDS camera module and software used in the upgraded Galileo NEO. The upgraded Galileo NEO is based upon the same design as the NEO Iris; that is, a Galileo Neo updated with the new IDS CMOS camera module and software version 3.xxx. The two instruments are identical; the only differences are model name, the exterior colors of the instruments, and whether the software indicates the device name as NEO Iris or Galileo NEO.

Comparison between the predicate and the proposed device demonstrated full equivalence in performance. Hence the upgraded Galileo NEO is substantially equivalent to the NEO Iris in terms of the assays and reagents available to run on the instrument and the test reporting data available to the user.

The proposed upgraded Galileo NEO is substantially equivalent to its predicate (NEO Iris) with respect, but not limited to, intended use, design, energy used/delivered, materials, performance, labeling, safety and effectiveness.