7.0 510(k) Summary

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510(k) Owner

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Contact Information

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Device Name

Trade/Device Name:	NEO Iris®	Galileo NEO®
Common Name:	Automated Blood Bank Analyzer	Automated Blood Bank Analyzer
Classification Name:	Automated blood grouping and antibody test system	Automated blood grouping and antibody test system
Unique Device Identifier (UDI):	10888234002321	10888234001041

Device Class

Trade/Device Name:	NEO Iris®	Galileo NEO®
Regulatory Class:	II	II
Product Code:	KSZ	KSZ
Regulation Number:	21CFR§864.9175	21CFR§864.9175
Classification Advisory Committee:	Hematology	Hematology
Review Advisory Committee:	Hematology	Hematology

Predicate Device Information

Trade/Device Name:	NEO Iris®	Galileo NEO®
Clearance:	BK210560	BK210562
Date Cleared:	April 12, 2021	April 12, 2021

Device Descriptions

The NEO Iris and Galileo NEO are robotic instruments 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 plate reader uses CMOS cameras to capture an image of the microplate from underneath. The software calculates a reaction value for each well based on a multi-feature image analysis. The software algorithm then assigns a result and interpretation to the wells based on predefined criteria associated with the calculated reaction value. The NEO Iris and Galileo NEO use software to drive instrument mechanics and data processing. The operator uses hardware in combination with the software to operate and maintain the instrument. All of NEO Iris's and Galileo 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.

Intended Use

The intended use of the modified devices, as described in the labeling has not changed as a result of the modifications.

NEO Iris:

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.

Galileo NEO:

The Galileo 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 Galileo NEO is for in vitro diagnostic use.

Technological Comparison to Predicate Device

Below is a summary of the technological characteristics of modified NEO Iris and Galileo NEO (proposed devices) compared to the predicate devices (BK210560 and BK210562).

Characteristic / Feature	Predicate	Predicate	Modified Devices
Trade/Device Name	NEO Iris BK210560 (cleared April 12, 2021)	Galileo NEO BK210562 (cleared April 12, 2021)	NEO Iris / Galileo NEO
Technology			
Camera	IDS camera module	IDS camera module	Identical
Software	NEO Iris Install Set 4.0.0.7	NEO Iris Install Set 4.0.0.7	Identical
PC Operating System	Microsoft Windows 10 (WIN10)	Microsoft Windows 10 (WIN10)	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 (no change)
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
Cytomegalovirus Antibody (IgG+IgM)	YES	YES	Identical
RH (C, E, c, e) and K Phenotyping	YES	YES	Identical
C3d DAT	NO	NO	YES
Jka/Jkb Phenotyping	NO	NO	YES

Clinical Performance

The objective of the clinical evaluation was to obtain performance data between the Jka and Jkb phenotyping assays on the NEO Iris instrument and the manual tube comparator method. Each donor/patient sample was tested on the instrument and by the manual tube method using the same lot of reagents.

A method comparison study was performed at two sites: one external site and Immucor as an internal site. Results are summarized in the following tables

Gamma-Clone Anti-Jk^a (Monoclonal):

Anti-Jk^a 696 Donor Samples		Resolved Results		PPA (Point Estimate)	100.00%
		Positive	Negative	PPA (95% 1-sided LCI)	99.50%
NEO Iris	Positive	458	0	NPA (Point Estimate)	100.00%
	Negative	0	238	NPA (95% 1-sided LCI)	98.04%

Gamma-Clone Anti-Jk^b (Monoclonal):

Anti-Jk^b 695 Donor Samples		Resolved Results		PPA (Point Estimate)	100.00%
		Positive	Negative	PPA (95% 1-sided LCI)	99.45%
NEO Iris	Positive	418	0	NPA (Point Estimate)	100.00%
	Negative	0	277	NPA (95% 1-sided LCI)	99.17%

Basis for Claim of Substantial Equivalence

The modified NEO Iris and Galileo NEO are substantially equivalent to the predicate devices (pre-modified NEO Iris and Galileo NEO) relative to technological characteristics of both instruments.

This Traditional 510(k) is submitted to modify legally marketed, predicate devices. The Indications for Use of the proposed devices are unchanged from the legally marketed, predicate devices. The intended use of the modified devices, as described in the labeling, has not changed; as a result of the modifications. Fundamental scientific technology of the proposed devices is unchanged from the legally marketed, predicate devices. There are no significant differences between the modified instruments and the predicates as related to the Intended Use or Principle of Operation.

With the exception of the addition of the phenotyping assay for the Jk^a and Jk^b blood group antigens; using Gamma-clone® monoclonal-based Anti-Jk^a and Anti-Jk^b Blood Grouping Reagents; the predicate and modified devices are identical.

The modified NEO Iris and Galileo NEO instruments are as safe and effective as the currently marketed predicates under BK210560 and BK210562 (respectively).