# 7.0 510(k) Summary

## Date Prepared

February 3, 2022

## 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® | 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: | BK210600 | BK210605 |
| Date Cleared: | September 3, 2021 | September 3, 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<br>BK210600<br>(cleared September 3, 2021) | Galileo NEO<br>BK210605<br>(cleared September 3, 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 |

| Characteristic / Feature | Predicate | Predicate | Modified Devices |
|---|---|---|---|
| **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.<br>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.<br>The Galileo NEO is for in vitro diagnostic use. | Identical<br>(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 |
| $Jk^a/Jk^b$ Phenotyping | YES | YES | Identical |
| S, s, $Fy^a$, $Fy^b$, and k Phenotyping | NO | NO | YES |

## Clinical Performance

### Anti-S:

Method comparison studies were performed at two (2) external sites and one (1) internal site. Immucor, Inc., as the manufacturer, was the internal site. The external sites were representative of blood collection establishments, hospital-based transfusion services, and/or clinical laboratories. Samples were tested with the reagent and also a comparator reagent. Test results were evaluated for agreement between reagents. Combined results from all sites are summarized in the following tables:
Note: Agreement between methods does not indicate which method is correct.
Assay performance represents NEO Iris and Galileo NEO (software version 3.1 or higher).

| Initial Results N=975 | | Comparator Reagent | | | |
|---|---|---|---|---|---|
| | | Positive | Negative | | |
| Anti-S | Positive | 545 | 2* | Positive Percent Agreement | 99.63% |
| | | | | PPA (95% 1-Sided LCI) | 98.85% |
| | Negative | 2** | 426 | Negative Percent Agreement | 99.53% |
| | | | | NPA (95% 1-Sided LCI) | 98.54% |

Discordant samples were further genotyped by DNA molecular testing (PreciseType™ HEA BeadChip).
*One (1) sample gave mixed-field reaction with comparator reagent; one (1) sample gave mixed-field reaction on NEO Iris.
**One (1) sample gave mixed-field reaction with comparator reagent; one (1) sample resulted negative on NEO Iris and positive with comparator reagent, and was negative by HEA BeadChip.
Resolved agreement is then PPA 99.58% (95% 1-sided LCI) and NPA 98.90% (95% 1-sided LCI).

Precision studies

Repeatability and Reproducibility were performed at three (3) sites by testing identical sample panels, containing positive and negative panel members in triplicate, testing two runs per day for five non-consecutive days. Results demonstrated 100% agreement for all positive and negative panel members.

**Anti-s:**

Method comparison studies were performed at two (2) external sites and one (1) internal site. Immucor, Inc., as the manufacturer, was the internal site. The external sites were representative of blood collection establishments, hospital-based transfusion services, and/or clinical laboratories. Samples were tested with the reagent and also a comparator reagent. Samples with Initial equivocal results were retest. Test results were evaluated for agreement between reagents. Combined results from all sites are summarized in the following tables:
Note: Agreement between methods does not indicate which method is correct.
Assay performance represents NEO Iris and Galileo NEO (software version 3.1 or higher).

| Initial Results N=975 | | Comparator Reagent | | | |
|---|---|---|---|---|---|
| | | Positive | Negative | | |
| Anti-s | Positive | 793 | 3* | Positive Percent Agreement | 100% |
| | | | | PPA (95% 1-Sided LCI) | 99.71% |
| | Negative | 0 | 179 | Negative Percent Agreement | 98.35% |
| | | | | NPA (95% 1-Sided LCI) | 95.80%† |

Discordant samples were further genotyped by DNA molecular testing (PreciseType™ HEA BeadChip). *Two (2) samples initially typed s– with comparator reagent; repeat test with comparator reagent and DNA were s+. One (1) sample initially type s– with comparator reagent; repeat tests with comparator reagent and NEO Iris were s–, DNA was s+. Resolved NPA 99.44% (97.39%† 95% 1-sided LCI). †The Lower 99% CI was not met due to the lower number of s– samples in the population, N=179.

Precision studies

Repeatability and Reproducibility were performed at three (3) sites by testing identical sample panels, containing positive and negative panel members in triplicate, testing two runs per day for five non-consecutive days. Results demonstrated 100% agreement for all positive and negative panel members.

**Anti-k:**

Method comparison studies were performed at two (2) external sites and one (1) internal site. Immucor, Inc., as the manufacturer, was the internal site. The external sites were representative of blood collection establishments, hospital-based transfusion services, and/or

clinical laboratories. Samples were tested with the reagent and also a comparator reagent. Samples with Initial equivocal results were retest. Test results were evaluated for agreement between reagents. Combined results from all sites are summarized in the following tables:
Note: Agreement between methods does not indicate which method is correct.
Assay performance represents NEO Iris and Galileo NEO (software version 3.1 or higher).

| **Initial Results N=834** | | **Comparator Reagent** | | | |
|---|---|---|---|---|---|
| | | Positive | Negative | | |
| **Anti-k** | Positive | 819 | 0 | Positive Percent Agreement | 100% |
| | | | | PPA (95% 1-Sided LCI) | 99.72% |
| | Negative | 0 | 15 | Negative Percent Agreement | 100% |
| | | | | NPA (95% 1-Sided LCI) | 85.77%* |

*The Lower 99% CI was not met due to the lower number of k– samples in the population, N=15.

Precision studies
Repeatability and Reproducibility were performed at three (3) sites by testing identical sample panels, containing positive and negative panel members in triplicate, testing two runs per day for five non-consecutive days. Results demonstrated 100% agreement for all positive and negative panel members.

**Anti-Fy$^a$:**

Method comparison studies were performed at two (2) external sites and one (1) internal site. Immucor, Inc., as the manufacturer, was the internal site. The external sites were representative of blood collection establishments, hospital-based transfusion services, and/or clinical laboratories. Samples were tested with the reagent and also a comparator reagent. Test results were evaluated for agreement between reagents. Combined results from all sites are summarized in the following tables:
Note: Agreement between methods does not indicate which method is correct.
Assay performance represents NEO Iris and Galileo NEO (software version 3.1 or higher).

| **Initial Results N=974** | | **Comparator Reagent** | | | |
|---|---|---|---|---|---|
| | | Positive | Negative | | |
| **Anti-Fy$^a$** | Positive | 673 | 5* | Positive Percent Agreement | 100% |
| | | | | PPA (95% 1-Sided LCI) | 99.66% |
| | Negative | 0 | 296 | Negative Percent Agreement | 98.34% |
| | | | | NPA (95% 1-Sided LCI) | 96.54% |

Discordant samples were further genotyped by DNA molecular testing (PreciseType™ HEA BeadChip). *All five (5) samples initially typed Fy(a–) with comparator reagent; repeat test with comparator reagent and DNA were Fy(a+). Resolved NPA 100% (99.23% 95% 1-side LCI).

Precision studies
Repeatability and Reproducibility were performed at three (3) sites by testing identical sample panels, containing positive and negative panel members in triplicate, testing two runs per day for five non-consecutive days. Results demonstrated 100% agreement for all positive and negative panel members.

**Anti-Fy$^b$:**

Method comparison studies were performed at two (2) external sites and one (1) internal site. Immucor, Inc., as the manufacturer, was the internal site. The external sites were representative of blood collection establishments, hospital-based transfusion services, and/or clinical laboratories. Samples were tested with the reagent and also a comparator reagent. Samples with Initial equivocal results were retest. Test results were evaluated for agreement between reagents. Combined results from all sites are summarized in the following tables:
Note: Agreement between methods does not indicate which method is correct.
Assay performance represents NEO Iris and Galileo NEO (software version 3.1 or higher).

| **Initial Results N=1236** | | **Comparator Reagent** | | | |
|---|---|---|---|---|---|
| | | Positive | Negative | | |
| **Anti-Fy$^b$** | Positive | 624 | 7* | Positive Percent Agreement | 98.89% |
| | | | | PPA (95% 1-Sided LCI) | 97.93% |
| | Negative | 7† | 598 | Negative Percent Agreement | 98.84% |
| | | | | NPA (95% 1-Sided LCI) | 97.84% |

Discordant samples were further genotyped by DNA molecular testing (PreciseType™ HEA BeadChip). *†One (1) sample in each category resolved in favor of the instrument result. Resolved PPA 99.05% (98.13% 95% 1-side LCI) and NPA 99.01% (98.05% 95% 1-side LCI).
†Three (3) samples typed as Fy(a+b+$^w$) [Fy$_{mod}$ (Fy$^x$)] due to the 265C>T SNP. Three (3) samples were unresolved as DNA testing gave low signal results (2) or was QNS for testing (1).
*One (1) sample had debris in the well and tested Fy(b–) upon retest. Four (4) samples were falsely positive due to misaligned instrument ROIs (Region of Interest); three (3) samples were Fy(b–) upon retest, one (1) sample remained Fy(b+) upon retest. One (1) sample was unresolved as DNA testing gave low signal results.

Precision studies
Repeatability and Reproducibility were performed at three (3) sites by testing identical sample panels, containing positive and negative panel members in triplicate, testing two runs per day for five non-consecutive days. Results demonstrated 100% agreement for all positive and negative panel members.

**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 S, s, Fy$^a$, Fy$^b$, and k blood group antigens; using Gamma-clone® monoclonal-based Anti-S, Anti-s, Anti-Fy$^a$, Anti-Fy$^b$ and Anti-k 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 BK210600 and BK210605 (respectively).