

## 8.0 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR§807.92.

### Applicant Information

Date Prepared: March 3, 2021  
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### Device Name

Trade/Device Name: NEO Iris  
Galileo NEO

### Device Class

Regulatory Class: II  
Product Code: KSZ (Automated Blood Grouping and Antibody Test System)  
Classification Advisory Committee: Hematology  
Review Advisory Committee: Hematology

### Predicate Device Information

NEO Iris (BK200474 / BK180243)  
Galileo NEO (BK200502)

### Device Description

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. Some assay protocols require multiple test wells for a given blood sample interpretation, such as ABO and Rh (D) typing. 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 NEO Iris and Galileo NEO 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**

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 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.

### **Summary of Modifications**

- The version of the Windows Operating System was changed from Windows 7 32-bit to Windows 10 64-bit
- The Instrument Control Software suite of applications was modified to be compatible with the Windows 10 64-bit Operating System
- The version of SQL Server was updated from SQL2008ExpressR2 to SQL2016Express
- The internet browser was updated from Internet Explorer 8 to Internet Explorer 11
- The model of computer used with the system was changed from the EliteDesk 800 G1 SFF to the HP RCTO Engage Flex Pro SFF
- Modifications to ArchiveFileRemoval-NEO
- Modifications to NEO Configuration Menu

The table below provides a detailed comparison of features between the predicate and modified devices:

Characteristic / Feature	Predicate	Predicate	Modified Devices
Trade/Device Name	NEO Iris BK200474 (cleared June 12, 2020) BK180243 (cleared November 7, 2018)	Galileo NEO BK200502 (cleared October 13, 2020)	NEO Iris / Galileo NEO
<b>Technology</b>			
Camera	IDS camera module	IDS camera module	Identical
Software	NEO Iris Install Set 3.0.1	NEO Iris Install Set 3.0.1	Identical
PC Operating System	Microsoft Windows 7 (WIN7)	Microsoft Windows 7 (WIN7)	Microsoft Windows 10 (WIN10)
<b>Indication For Use</b>			
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)
<b>Regulatory</b>			
Product Code	KSZ	KSZ	Identical
Regulation Number	21CFR§864.9175	21CFR§864.9175	Identical
<b>Specimen Types</b>			
Plasma	YES	YES	Identical
Serum	YES	YES	Identical
Red Cells	YES	YES	Identical
<b>Assay Types</b>			
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

### Statement of Substantial Equivalence

This Special 510(k) is submitted to modify legally marketed devices (predicates). Immucor is the holder of the 510(k)s for the predicate devices. The Indications for Use of the proposed devices are unchanged from the legally marketed devices (predicates). The intended use of the modified devices,

as described in the labeling, has not changed as a result of the modifications. Finally, fundamental scientific technology of the proposed devices is unchanged from the legally marketed devices (predicates). There are no significant differences between the modified instruments and the predicates as relates to Intended Use or Principle of Operation. With the exception of the PC Operating System version, 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 BK200474 and BK180243, and BK200502 (respectively).