Special 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

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Device Information

Trade Name:	Galileo Neo®
Model Number:	Product Code 0064599
Software Version:	Version 2.2 (Rev. 2)/ICS 1.5.10.7/DMS 2.09 SP2
Common Name:	Automated Blood Bank System
Classification Name:	Automated blood grouping and antibody test system
Regulation Number:	21CFR 864.9175
FDA Product Code:	KSZ

Predicate Device

Galileo Neo® Automated Blood Bank System, 510(k) number BK100033, cleared on August 23, 2010.

Device Description

The Galileo Neo, hereinafter NEO, is an automated immunohematology instrument. The NEO is a microprocessor-controlled instrument designed to fully automate immunohematological *in vitro* diagnostic testing of human blood. The NEO automates test processing, result interpretation and data management functions. The NEO is designed to automate standard immunohematology assays using a microplate-based platform. Assays include, but are not limited to, ABO grouping and Rh (D) typing, detection/identification of IgG red blood cell antibodies, compatibility testing, red blood cell phenotyping, antigen screening and infectious disease screening such as cytomegalovirus (CMV).

The NEO is a closed system intended for use only with the reagents specified in Appendix 1 of the Galileo NEO Operator Manual.
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.

Intended Use

The Galileo Neo (NEO) is a microprocessor-controlled instrument to fully automate immunohematology in vitro diagnostic testing of human blood. The NEO automates test processing, result interpretation and data management functions. The 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, antigen screening and infectious disease screening, such as cytomegalovirus (CMV). The antigen screening assays provide guidelines for the user to select antisera or dilute commercial blood grouping reagents as a mechanism to pre-screen for antigen negative blood units that can then be subjected to confirmation using a licensed method.

The NEO is intended for use only with the reagents described in Attachment 1 for Galileo Neo Operator Manual.

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Comparison to Predicate Device's Technological Characteristics

A comparison between the proposed Galileo Neo and its predicate is presented in the table below. There are no changes related to the technological characteristics of the instrument and no change to the intended use. The changes described in this submission do not impact any technological characteristics or the instrument's intended use.

Intended Use	**Galileo Neo (BK100033)**	**Galileo Neo (proposed device)**
Automated immunohematology system for in vitro diagnostic use	X	X
Tests Performed	**Galileo Neo (BK100033)**	**Galileo Neo (proposed device)**
ABO & Rh Typing	X	X
Antibody Screen	X	X
Antibody Identification	X	X
IgG Crossmatch	X	X
Direct Antiglobulin Test	X	X
Antigen Typing	X	X
CMV Antibody Testing	X	X
Syphilis Testing *	X	X
Read test reactions by digital image analysis	X	X
Test Result Interpretation	X	X
Technical Characteristics	**Galileo Neo (BK100033)**	**Galileo Neo (proposed device)**
User interface using computer workstation	X	X
System security requires user passwords for access	X	X
Testing performed on plasma	X	X
Testing performed on serum	X	X
Testing performed on red blood cells	X	X
Barcode read on reagent and samples to on firm presence and location on the instrument	X	X
Barcode read of reagent lot number and expiration date	X	X
Manual entry of sample or reagent barcode requiring double blind entry	X	X
Acceptable reagent vial size	10mL** and 57mL	10mL** and 57mL
Sample and reagent volume verification at aspiration	X	X
Programmed to track volume or usage of each reagent vial or plate	X	X
Prepares sample red cell suspension	X	X
Multiple vials of same reagent can be loaded on instrument. When empty instrument switches to	X	X

second vial.		
Maintains red cell suspensions by agitation	X	X
Walk away testing capability	X	X
Instrument will discontinue operation if liquid waste is full	X	X
Incubation duration and temperature are monitored	X	X
Plate washed with controlled volume and flow rate	X	X
Washer dispense / aspiration checks	Fully Automated	Fully Automated
Centrifuge performed at specified rpm values and durations	X	X
Pipettor check maintenance function	Fully Automated	Fully Automated
Error message for dispense verification discrepancy prior to result reading	X	X
Blood type test results interpreted against standard industry interpretation tables	X	X
Can be interfaced to laboratory information systems	X	X
*TPHA Screen cleared under BK120021; Product is currently discontinued.		
** Reagent volume in 10mL vial may vary		

Nonclinical Performance Testing

Non-clinical studies were conducted in-house at Immucor to verify that the NEO's performance was not impacted by the changes described in this submission. Regression analysis and Verification testing data showed no impact on the instrument's performance characteristics.

Statement of Substantial Equivalence

Review of the intended use, technical characteristics, and the results of non-clinical performance testing demonstrates that the Galileo Neo (NEO) is as safe, as effective, and performs as well as or better than the predicate device.