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:	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:	ORTHO VISION™ Max Analyzer
Clearance:	BK160058 (cleared October 21, 2016)

Device Description

The Galileo NEO, or NEO, is an automated immunohematology instrument. The NEO is a microprocessor-controlled instrument designed 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, 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.

Technological Comparison to Predicate Device

Below is a summary of the technological characteristics of modified Galileo NEO (proposed device) compared to the predicate device (ORTHO VISION™ Max Analyzer).

Characteristic / Feature	Predicate	New/Modified Device
Trade/Device Name	ORTHO VISION™ Max Analyzer (BK160058)	Galileo Neo
Indication For Use		
Automated immunohematology instrument for in vitro diagnostic use	ORTHO VISION™ Max Analyzer is an instrument designed to automate in vitro immunohematology testing of human blood utilizing ID-MTS™ gel card technology. ORTHO VISION™ Max Analyzer automates test processing functions including liquid pipetting, reagent handling, incubation, centrifugation, reaction grading and interpretation and data management requirements using cards and digital image processing. ORTHO VISION™ Max Analyzer can be used as a standalone instrument or interfaced to the customer's Laboratory Information System (LIS).	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.
Regulatory		
Product Code	KSZ	KSZ
Regulation Number	21CFR§864.9175	21CFR§864.9175
Specimen Types		
Plasma	YES	YES
Serum	YES	YES
Red Cells	YES	YES
Assay Types		
ABO/RH	YES	YES
Antibody Detection/Identification	YES	YES
Crossmatch	YES	YES
Direct Antiglobulin Test	YES	YES
Antigen Testing	YES	YES
QC Testing	YES	YES
Serial Dilution for Titration Studies	Tested against user-selected red blood cells (e.g. A1, A2, B, Fy(a+), etc. Reagent Red Blood Cells)	Tested against A1, A2 and B Reagent Red Blood Cells

Clinical Performance

The performance of the ABO Titration assays was evaluated at two (2) external sites and at Immucor, Inc. as an internal site, and the results obtained with the ABO Titration assays on the Galileo NEO met the acceptance criteria.

All assays met the acceptance criteria of 100% agreement that the titer results determined by Galileo NEO Automated titration assays were within ±2 doubling dilution(s) when compared to the titer results determined by manual dilution except for the Low Titer IgG anti-B (LTGB) and High Titer IgG anti-B (HTGB) assays. For the LTGB assay, one sample was discordant for an overall percent agreement of 98.93% (n=93, 95.00% 95% LCI). The manual dilution titer was 16 and the Galileo Neo automated titer was 128; the sample was QNS for repeat testing per the protocol. For the HTGB assay, one sample was discordant for an overall percent agreement of 91.67 % (n=12, 66.13% 95% LCI). The manual dilution titer was 32 and the Galileo NEO automated titer was 256; the sample was QNS for repeat testing per the protocol.

Method Comparison Summary of All Assay Results		Equal or within ±1 Doubling Dilution			Equal or within ±2 Doubling Dilutions		
Assay	N	n	%	LCI	n	%	LCI
TMA1	93	92	98.93%	95.00%	93	100.00%	96.83%
TMA2	93	87	93.55%	87.67%	93	100.00%	96.83%
TMB	93	89	95.70%	90.43%	93	100.00%	96.83%
TLGA1	93	92	98.93%	95.00%	93	100.00%	96.83%
THGA1	19	19	100.00%	85.41%	19	100.00%	85.41%
TLGA2	93	88	94.62%	89.03%	93	100.00%	96.83%
TLGB	93	86	92.47%	86.33%	92*	98.93%	95.00%
THGB	12	11*	91.67%	66.13%	11*	91.67%	66.13%

*Discordant sample was QNS for repeat testing

For the reproducibility study, all titer results were within two-doubling dilutions of the expected or consensus titer for all assays.

Reproducibility Summary of All Assay Results		Equal or within ±1 Doubling Dilution			Equal or within ±2 Doubling Dilutions		
Assay	N	n	%	LCI	n	%	LCI
TMA1	180	180	100.00%	98.35%	180	100.00%	98.35%
TMA2	180	180	100.00%	98.35%	180	100.00%	98.35%
TMB	180	165	91.67%	87.46%	180	100.00%	98.35%
TLGA1	180	179	99.44%	97.39%	180	100.00%	98.35%
THGA1	60	60	100.00%	95.13%	60	100.00%	95.13%
TLGA2	180	177	98.33%	95.75%	180	100.00%	98.35%
TLGB	180	175	97.22%	94.25%	180	100.00%	98.35%
THGB	60	60	100.00%	95.13%	60	100.00%	95.13%

Basis for Claim of Substantial Equivalence

The modified Galileo NEO is substantially equivalent to the predicate device in a comparison of the technological characteristics of both instruments. Notably both may be used to perform automated Serial Dilutions for Titration Studies using Reagent Red Blood Cells.

Additionally, in clinical performance evaluations the modified Galileo NEO has been demonstrated to meet the acceptance criteria whereby Automated Titration assay results were within two (2) doubling dilution(s) when compared to the titer results determined by manual dilution except for the TLGB/THGB assays. One sample produced discordant results that varied by three (3) doubling dilutions; the sample was QNS for repeat testing. Although

the TLGB and THGB assays did not meet the acceptance criteria of 100% agreement within ±2 doubling dilutions due to one discordant sample, which was QNS for repeat testing, the reproducibility and overall percent agreement for the assays are still clinically acceptable.