Revised 510(k) Summary

Applicant Information:

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Device Information:

Device Name: Galileo Echo™
Common Name: Automated Blood Bank Analyzer
Classification: 21 CFR 864.9175, Class II,
Classification Name: Automated blood grouping and antibody test system,

Device Description and Intended Use
The Galileo Echo™ is a microprocessor-controlled instrument designed to fully automate immunohematology in vitro diagnostic testing of human blood. The Galileo Echo automates test processing, result interpretation and data management functions. The Galileo Echo is designed to automate standard immunohematology assays using a microstrip-based platform. Assays include ABO grouping and Rh (D) typing, detection/ identification of IgG red blood cell antibodies, compatibility testing and red blood cell phenotyping.

The Galileo Echo is a closed system intended for use only with the reagents specified in the Galileo Echo Operator Manual.

All of the Galileo Echo 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.

Predicate Devices:
Immucor Galileo® (BK0400130)
Immucor ABS2000 (BK000024),
Ortho ProVue, Software Version 2.10(BK030023),
Comparison to Predicate Devices:

A comparison between Galileo Echo and predicate devices is presented in the table below. The devices are compared based on technological characteristics and intended use.

Comparison of Technological Characteristics & Intended Use

Intended Use	Galileo Echo	Galileo	ABS 2000	Ortho ProVue
Automated immunohematology analyzer for in vitro diagnostic use	X	X	X	X
Tests Performed:				
ABO & Rh Typing	X	X	X	X
Antibody Screen	X	X	X	X
Antibody Identification	X	X		X
IgG Crossmatch	X	X		X
Direct Antiglobulin	X	X		X
Antigen Typing	X			X
Read Test reactions by digital image analysis	X	X		X
Test Result Interpretation	X	X	X	X

Technical Characteristics Comparison

Technical Characteristics	Galileo Echo	Galileo	ABS 2000	Ortho ProVue
User interface using computer workstation	X	X	X	X
System security requires user passwords for access	X	X	X	X
Testing performed on plasma	X	X	X	
Testing performed on serum				X
Barcode read on reagent and samples to confirm presence and location on the instrument	X	X	X	X
Microstrip barcode read of reagent lot, expiration date and unique sequential number for strip.	X			
Microstrip barcode read of reagent lot, expiration date and unique sequential number for strip.	X			
Barcode read of reagent lot number and expiration date	X	X	X	X
Manual entry of sample or reagent barcode requiring double blind entry	X	X		X
Acceptable reagent vial size	10mL[1]	10mL[1]	10mL[1]	3, 5 and 10mL
Sample and reagent volume verification at aspiration	X	X	X	
Programmed to track volume or	X	X		

Technical Characteristics	Galileo Echo	Galileo	ABS 2000	Ortho ProVue
usage of each reagent vial or plate				
Prepares sample red cell suspension	X	X	X	X
Multiple vials of same reagent can be loaded on instrument. When empty instrument switches to second vial.	X	X	X	X
Maintains red cell suspensions by agitation	X	X	X	X
Walk away testing capability	X	X	X	X
Instrument will discontinue operation if liquid waste is full	X	X		X
Incubation duration and temperature are monitored	X	X	X	X
Centrifuge performed at a consistent rpm range and duration	X	X	X	X
Error message for dispense verification discrepancy prior to result reading	X	X		X
Blood type test results interpreted against standard industry interpretation tables	X	X	X	X
Can be interfaced to laboratory information systems	X	X	X	X

[1] Reagent volume in 10mL vial may vary

Performance Testing - Clinical

Clinical studies were conducted at six clinical test sites that included transfusion services, donor centers and clinical laboratories to validate that the Galileo Echo performs as expected when placed in end user facilities. The clinical test sites were selected to capture a diverse sample population based upon geographic location and facility demographics.

Parallel testing between the Galileo Echo and established reference methods (Galileo and/or manual tube) was performed with de-identified, surplus samples (patient and donor) by trained operators from each site. The objectives of these studies was to demonstrate that: 1) end users, with proper training, could use the Galileo Echo to perform the in vitro diagnostic tests defined for Galileo Echo and 2) the testing with specified reagent on the Galileo Echo would generate results comparable to established reference methods.

The comparison of the test results by the Galileo Echo method to the reference method is detailed in the following table.

Determination	Assay	Number of Samples Tested	Agreement	95% Lower Confidence Bound (1-sided)
ABO/Rh cell grouping	Donor, Confirm, Pediatric	746	99.9% (745/746)	99.4%
ABO/Rh cell and serum grouping	Group, Group Screen	5029	99.2% (4990/5029)	99.0%
Weak D	Weak D	583	99.0% (577/583)	98.0%
Antibody Detection	Group Screen, Screen	5091	98.9% (5033/5091)	98.6%
Antibody Identification	Ready ID	104	94.2%* (98/104)	88.9%
Compatibility	Crossmatch	1888	97.8%** (1847/1888)	97.2%
DAT	DAT	654	97.4%*** (637/654)	96.1%
C antigen type	Ag_CcEeK	961	100% (961/961)	99.7%
c antigen type	Ag_CcEeK	961	99.9% (960/961)	99.5%
E antigen type	Ag_CcEeK	961	100% (961/961)	99.7%
e antigen type	Ag_CcEeK	961	99.9% (960/961)	99.5%
K antigen type	Ag_CcEeK	961	99.8% (959/961)	99.4%

* The % agreement was affected by the small population size and lack of sufficient sample volume for repeat or investigative testing. The performance of the antibody identification assay is expected to be similar to antibody detection assays.

** The overall % agreement was affected by numerous samples that lacked sufficient volume for repeat or investigative testing. Additional testing of 871 crossmatch combinations, data included above, resulted in 99.4% agreement (98.8% LCB), between the Galileo Echo and the Reference method.

*** Seven samples were Galileo Echo positive and negative by the reference method. These seven samples were positive by a Gel DAT assay.

The results of the clinical validation support the conclusion that the Galileo Echo blood bank analyzer is safe and effective for the automated determination of ABO grouping and Rh (D) typing, detection/identification of IgG antibodies to red cells, compatibility testing and red blood cell phenotyping. The results of the clinical studies demonstrated that end users, with proper training, could use the Galileo Echo to perform the in vitro diagnostic tests with specified reagents for the instrument and that the Galileo Echo would generate results comparable to established reference methods. In conclusion, these studies demonstrate that the Galileo Echo is an effective automated method for performing immunohematological in vitro diagnostic testing.