

## 510(k) Summary

### Applicant Information:

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### Device Information:

Device Name: Galileo®  
Software version 1.3.6 SP4 / DMS 1.26

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 is a microprocessor-controlled instrument designed to fully automate immunohematology in vitro diagnostic testing of human blood. The Galileo automates test processing, result interpretation and data management functions. The Galileo 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 and infectious disease screening such as syphilis and cytomegalovirus (CMV).

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

All of Galileo'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.

**Predicate Devices:**

Immucor ABS2000 (BK000024),  
 Ortho Pro Vue, Software Version 2.10(BK030023),  
 Olympus PK 7200, Software Version 3.7 (BK020024-0)

**Comparison to Predicate Devices:**

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

Intended Use	Galileo	ABS 2000	Ortho Provue	Olympus PK 7200
Automated immunohematology analyzer for in vitro diagnostic use	X	X	X	X
<b>Tests Performed:</b>				
ABO & Rh Typing	X	X	X	X
Antibody Screen	X	X	X	
Antibody Identification	X		X	
Crossmatch	X	X		
IgG Crossmatch	X		X	
Direct Antiglobulin	X		X	
Antigen Typing	X		X	
CMV Antibody Testing	X			X
Syphilis Testing	X			X
Read Test reactions by digital image analysis	X		X	X
Test Result Interpretation	X	X	X	X

Technical Characteristics	Galileo	ABS 2000	Ortho	Olympus PK 7200
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	X
Barcode read on reagent and samples to confirm presence and location on the instrument	X	X	X	X
Barcode read of reagent lot number and expiration date	X	X	X	
Manual entry of sample or reagent barcode requiring double blind entry	X		X	
Acceptable reagent vial size	10mL and 57mL	10mL	3, 5 and 10mL	
Sample and reagent volume verification at aspiration	X	X		X
Programmed to track volume or usage of each reagent vial or plate	X			
Prepares sample red cell suspension	X	X	X	X

Technical Characteristics	Galileo	ABS 2000	Ortho	Olympus PK 7200
Multiple vials of same reagent can be loaded on instrument. When empty instrument switches to second vial.	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	
Incubation duration and temperature are monitored	X	X	X	X
Centrifuge performed at a consistent rpm range and duration	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

### Summary of Clinical Tests

Comparison of the test results by the Galileo method to the reference method was performed for each assay and is detailed in Table 1. The number of samples reported as "no interpretation", "discrepant" and the percent agreement to the reference method was calculated for all assays performed on the Galileo.

**Table 1: Initial Test Results:**

Assay	Number of Samples Tested	Number of No Interpretation Results	Number of Discrepant Results	% Agreement to Reference Method
For ABORH	242	0	0	100.0
ABORH	3623	35	2	99.0
Weak D	568	14	3	97.0
Pool Cell	1606	2	2	99.8
2 Cell	1453	40	9	96.6
4 Cell	500	13	15	94.4
Ab ID	136	0	8	94.1
IS_XM	55*	0	0	100.0
IgG_XM	50**	0	3	94.0
DAT	137	0	2	98.5

The samples reported as "No Interpretation of Results" included samples that the instrument identified as no type determined (NTD) and sample results flagged as invalid (INV) due to automated process controls. The instrument is designed to give no interpretation when it detects conditions that could compromise the accuracy of results such as sample condition (excessive hemolysis, icterus, lipemia), clots or liquid level detection errors. Results flagged as invalid are considered a safety control to prevent the reporting of incorrect results. Seventy percent of the samples within this category were due to automated process controls indicating that the instrument detected situations that could lead to potentially incorrect results.

The samples reported as "Discrepant" included samples demonstrating different test interpretations between the Galileo method and the reference method. Further investigation revealed that sixty-one percent of the discrepancies were due to incorrect test results of the reference method.

Comparison of the test results by the Galileo method to the expected results was performed for each assay after repeat testing. Samples which did not give an interpretation (i.e. hemolyzed, lipemic, icteric, etc) or samples associated with a limitation of the reagent (as specified in reagent labeling, i.e. passive anti-D) were excluded from the study. The comparison by assay is detailed in Table 2.

#### Final Test Results after Repeat Testing:

Assay	Number of Samples After Exclusion	Number of No Interpretation Results	Number of Discrepant Results	% Agreement to Expected Results
For ABORH	242	NA	NA	100.0
ABORH	3620	10	0	99.7
Weak D	561	0	0	100.0
Pool Cell	1606	0	2	99.9
2 Cell	1439	0	3	99.8
4 Cell	497	0	1	99.8
Ab ID	133	0	0	99.3*
IS_XM	55**	NA	NA	100.0
IgG_XM	50***	0	0	100.0
DAT	137	0	1	99.3

\* Two samples were excluded from the final agreement calculation. These samples were from pregnant Rh negative women who most likely had received antenatal Rh immune globulin. The Capture-R Ready Screen package insert contains a limitation that states that passively administered anti -D may fail to react by Capture- R Ready Screen. In the reference method all samples demonstrated an anti-D specificity. When tested on the Galileo, the two samples showed variable reactivity with D+ cells.

\*\* 55 Patient/Donor Combinations (11 patients using 20 donor units)

\*\*\* 50 Patient/Donor Combinations (10 patients using 35 donor units)

#### Conclusions Drawn from Studies

The results of the clinical validation support the conclusion that the Galileo 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 direct antiglobulin testing for in vivo IgG sensitization of red cells. The results of the clinical

studies demonstrated that end users, with proper training, could use the Galileo to perform the in vitro diagnostic tests defined for Galileo and the testing with specified reagents on the Galileo would generate results comparable to established reference methods. In conclusion, these studies demonstrate that the Galileo is an effective automated method for performing immunohematological in vitro diagnostic testing.