4. 510(k) SUMMARY

Applicant Information:

Date Prepared:	August 10, 2007
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Device Information:

Device Name:	Galileo®
Common Name:	Automated Blood Bank Analyzer
Classification:	21 CFR 864.9175, Class II (BK040013)
Classification Name:	Automated blood grouping and antibody test system

Predicate Devices:

Ortho Pro Vue, Software Version 2.10(BK030023)

Olympus PK 7200, Software Version 3.7 (BK020024-0)

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).

This 510(k) summary applies to use of the Reverse ABO Group assay using the Galileo instrument. The Reverse ABO Group Assay only tests the reverse ABO type rather than both the forward and reverse type. This assay is created by modifying the ABO_Rh assay to only include controls and the reverse typing test wells. The test parameters are not modified. The cutoffs for the equivocal range are modified to expand the equivocal range. This was done to improve safety by reducing the risk of mistypes. The Galileo is a closed system intended for use only with the reagents specified in the Galileo Operator Manual.

The Reverse ABO Blood Group assay is intended to screen for reverse group antibodies in plasma. This provides a presumptive indication of the red blood cell ABO group for the individual from which the plasma was collected. The absence of the corresponding forward group test subjects the results of this assay to several potential sources of error. These include serological factors due to the donor's age, immunological state, transfusion or transplantation status or disease sates. Sample related conditions such as higher-than-expected levels of lipids, bilirubin, free plasma hemoglobin, clots or aggregates may also be a factor. This assay can not be used (alone) to determine the ABO group as part of pre-transfusion testing in a patient population, or to determine ABO group for red blood cell products intended for transfusion.

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.

Predicate Devices:

Ortho Pro Vue, Software Version 2.10(BK030023),

Olympus PK 7200, Software Version 3.7 (BK020024-0)

Comparison of Technological Characteristics & Intended Use

Intended Use	Galileo	Ortho ProVue	Olympus PK 7200
Automated immunohematology analyzer for in vitro diagnostic use	X	X	X
Tests Performed:			
ABO & Rh Typing	X	X	X
Antibody Screen	X	X	
Antibody Identification	X	X	
Crossmatch	X		
IgG Crossmatch	X	X	
Direct Antiglobulin	X	X	
Red Blood Cell Phenotyping	X	X	

Intended Use	Galileo	Ortho ProVue	Olympus PK 7200
RBC Antigen Screening	X	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

Technical Characteristics Comparison

Technical Characteristics	Galileo	Ortho ProVue	Olympus PK 7200
User interface using computer workstation	X	X	X
System security requires user passwords for access	X	X	X
Testing performed on plasma	X		X
Testing performed on serum		X	X[1]
Barcode read on reagent and samples to confirm presence and location on the instrument	X	X	X[2]
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[3] and 57mL	3, 5 and 10mL[3]	
Sample and reagent volume verification at aspiration	X		X
Programmed to track volume or usage of each reagent vial or plate	X		
Prepares sample red cell suspension	X	X	X
Multiple vials of same reagent can be loaded on instrument. When empty instrument switches to second vial.	X	X	
Maintains red cell suspensions by agitation	X	X	X
Walk away testing capability	X	X	X
Instrument will discontinue operation if liquid waste is full	X	X	
Incubation duration and temperature are monitored	X	X	X
Centrifuge performed at a consistent rpm range and duration	X	X	

Technical Characteristics	Galileo	Ortho ProVue	Olympus PK 7200
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
Can be interfaced to laboratory information systems	X	X	X

[1] **CMV and Syphilis repeat only**
[2] **Samples only**
[3] **Reagent volume in 10mL vial may vary**

Bench Studies

In-house bench studies and verifications determined that the performance of the ABO reverse assay (Rev_ABO) was substantially equivalent to the ABO_Rh assay, which include both forward and reverse type testing. Base on a population of 650 samples, the initial percent agreement was 98.6% (630/ 639) with a lower 1-side 95% confidence limit of 97.6%. The discrepant results were caused by an invalid result (1) or equivocal results (8) interpreted as no type determined (NTD) in either the Rev_ABO or ABO_Rh assays. After repeat testing of discrepant samples, the percent agreement was 99.8% (638/639) with a lower 1-side 95% confidence limit of 99.3%.

The Rev_ABO assay does not have the built-in security of the forward type to verify the back type. Therefore, this assay should be used only in situations where sample red cells are unavailable. The instrument operator manual reflects the inherent risks of this assay.